



Analysis and Feasibility Assessment Regarding EU systems for Tracking and Tracing of Tobacco Products and for Security Features

Final Report

***No EAHC/2013/Health/11
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*Eurogroup Consulting and Sovereign Border Solutions
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SOVEREIGN
BORDER SOLUTIONS

EUROPEAN COMMISSION

Directorate-General for Health and Food Safety
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1 EXECUTIVE SUMMARY

The following document serves as the Final Report to the European Commission's Consumers, Health and Food Executive Agency (CHAFAEA) in response to the tender n° EAHC/2013/Health/11 concerning the provision of an analysis and feasibility assessment regarding EU systems for tracking and tracing of tobacco products and for security features (hereinafter "the Project"). As per the original tender, this report includes the findings and recommendations with respect to the overall Project and all related deliverables. The Final Report incorporates the first and second stages of the Project. This Executive Summary serves as a summary to the Final Report and is available in English and French.

1.1 PROJECT CONTEXT

As per the Tender¹, the Project clearly defined the deliverables, specific tasks within each, and meetings and workshops with the EU Commission, with associated milestones and deadlines for the entire Project. This final report is organized to align with the key tasks identified in the Tender requirements. Figure 1 provides a graphic depiction of the Project deliverables that were divided up into two main categories: traceability and security features. The overall project foundation was established in Tasks 1 and 2, which consisted of:

- A **Market Assessment** and mapping of existing traceability and security feature solutions suitable for tobacco products;
- Development of a comprehensive **Problem Statement**, taking into consideration the regulatory reference points (e.g., TPD), as well as the requirements of multiple stakeholders, particularly those dealing with illicit trade;
- Development of four possible alternative **Options** for both tracking and tracing and security features, and were reviewed and finalized by the Client; and,
- **Benchmarking** with existing track and trace systems currently in operation within the tobacco domain and within other industries.



Figure 1 - Key Project Tasks (from Tender Technical Requirements)

Tasks (3-6) required that the four options for traceability and security features be subject to analyses, as per the Problem Statement, as well as through **Cost Benefit Analyses**. These analyses also required a detailed analysis of high-level requirements related to data storage contracts with independent third parties.

¹ Call for Tender: 2013/EAHC/HEALTH/11, "Analysis and Feasibility assessment regarding EU systems for tracking and tracing of tobacco products and for security features", Specifications Attached to the Invitation to Tender, § 3.3

1.2 PROJECT METHODOLOGY

The Project required extensive research, as well as direct contact with key stakeholders and solution providers. Desk research consisted of gathering all pertinent market studies, reports, product brochures, case studies and other relevant documentation. 274 solution providers were identified and contacted directly to obtain the relevant contact person to participate in engagements related to the Project. A database of contacts (phone, email) was compiled and an online survey tool was created. The online survey tool provided the capability to utilize dynamic surveys that allowed participants to fill out only those elements pertaining to their organisation and solution. It also allowed the team to closely monitor survey responses and overall participation.

During the course of the Project, four different surveys were developed and distributed giving respondents no less than four weeks to respond for each. In nearly all cases the deadline was extended and exceptions were granted to accommodate late responses; the last survey was received on the 5th of December 2014 (five months after the survey closing period). Data validation was conducted via direct contact with respondents where necessary and consisted of email and conference calls. A complete log, documenting the extensive engagement with stakeholders is included as an annexure to the Final Report (See Annexure 7).

Given the diversity and large number of solution and related providers across a wide range of applications and industries (e.g., pharmaceuticals, consumer goods, etc.), the research objectives were focussed on gathering "real" vs. "marketing" facts. It also required that, in the process of creating a logical method evaluating the market, study participant's confidentiality be protected. Given budget and time constraints, the possibility to interact with individual solution providers was limited and travel resources related to site visits were allocated in a targeted manner to review existing solutions currently in operation in the tobacco domain.

A configurable model was built to serve as an analysis tool to analyse the data received from the surveys. This tool was based on market-leading methodologies related to technology analyses and incorporated the essence of the Problem Statement. The tool also facilitated the graphical plotting of solutions on a consistent and objective basis, as per the requirement to map solutions as contained in the tender. The model is described in further detail in Section 1.3.2 below.

1.2.1 DEFINING THE PROBLEM STATEMENT

The core foundation for the project and one of the first deliverables of the Project was to develop a comprehensive Problem Statement that provided the basis from which to conduct the Project analyses. As set out in the Project specifications, the Problem Statement took the following into account:

- The estimated size and context of the illicit market in the EU;
- Dynamics of tobacco supply chains (internal production, import, export, transit etc.);
- Agreements between the EU and various Member States with the tobacco industry;
- EU and Member State policies, key stakeholders (including health, law enforcement entities, Customs etc.); and,



Figure 2 - Key Stakeholders

- Legal obligations derived from the Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC (TPD) (Article 15 and 16) as well as the FCTC Protocol.

Combined, these factors, which include the interests of key stakeholders and legal considerations, established the basis from which to evaluate possible solution options.

1.2.2 ILLICIT TOBACCO TRADE IN THE EU

Measuring illicit trade in tobacco is methodologically challenging for various reasons. First, it is an illegal activity and illicit traders attempt to remain invisible and are unlikely to record their activities. Also, for security reasons, data on illicit trade is usually difficult to obtain, as law enforcement agencies often prefer not to publicise the scope of their activity. Furthermore, all methods to estimate illicit trade have their limitations and not all studies clearly describe their methodology or these limitations.

Transparent, public data on illicit tobacco trade is missing in most European countries. KPMG, a major consultancy and professional services firm, conducted research on illicit trade as a part of the agreement between the EU and Philip Morris International (PMI). According to KPMG, contraband trade accounted for 9.9% of total consumption in 2010 and 11.1% in 2012.² Critique of the KPMG estimates includes, among others, that the methodology for the collection of the empty packs in the report is insufficiently explained to judge its validity and that the report relies heavily on expertise and data provided by the tobacco industry³.

During the period 1996-2012, cigarette seizures in the European Union were highest in 1999-2000 (around 6 billion a year), when certain tobacco companies were accused of being involved in the smuggling operations.

Table 1. Cigarette seizure data in the EU-15 (1996-2003), EU-25 (2004-2006) and EU-27 (2007-2012).

EU-15		EU-25		EU-27	
Year	Billion cigarettes	Year	Billion cigarettes	Year	Billion cigarettes
1996	3.1	2004	4.1	2007	4.8
1997	2.6	2005	4.4	2008	4.6
1998	4.7	2006	4.6	2009	4.7
1999	5.7			2010	4.7
2000	6.2			2011	4.4
2001	4.8			2012	3.8
2002	3.6				
2003	3.3				

Source: European Anti-Fraud Office (OLAF)

However, it should be noted that large seizure data have their limitations and provide only an indication of trends in the illicit market. Seizures are a function of law

² KPMG. Project Star 2012 Results [Internet]. 2013;

³ Gilmore AB, Rowell A, Gallus S, Lugo A, Joossens L, Sims M. Towards a greater understanding of the illicit tobacco trade in Europe: a review of the PMI funded "Project Star" report. Tob Control. 2013 Dec 11;

enforcement activity and may vary according their efficiency and intensity. In addition, they don't take into account the illicit trade of smaller consignments (below 100.000 cigarettes).

1.2.3 THE AGREEMENTS WITH FOUR MAJOR TOBACCO COMPANIES

In July 2004, the EU and 10 Member States concluded enforceable and legally binding anti-smuggling agreements with PMI, which agreed to pay the European Commission (EC) \$1 billion over 12 years. Similar agreements were concluded with JTI in December 2007 (agreed payments: \$400 million), with British American Tobacco (BAT) in July 2010 (agreed payments: \$200 million) and with Imperial Tobacco Limited (ITL) in September 2010 (agreed payments: \$300 million). The agreements require the four companies to control future smuggling through a range of measures, which included controlling the distribution system and contractors supplied, and implementing tracking and tracing measures. The current track and trace solution which has been rolled out on some production lines is a result of this agreement and has since been incorporated into the industry's solution, including the Codentify code assignment module. Although the first Agreement originally covered only 10 Member States, currently the EU Commission and 27 Member States have signed the four Agreements, and one Member State has signed two of the agreements.

1.2.4 THE EU POLICY TO COMBAT ILLICIT TRADE OF TOBACCO PRODUCTS

On 6th June 2013, the European Commission published its communication to step up the fight against illicit trade in tobacco products. The communication sets out the Commission's proposals for a comprehensive EU strategy to tackle this illicit trade. The communication is accompanied by an action plan, which contains 50 measures, and time lines and outcome measures to be developed and implemented over the next two years.⁴ The communication lists a range of approaches to be implemented by the EU institutions (Commission, Council, Parliament and the Member States).

The planned measures include:

- More investment in equipment and IT tools to protect borders;
- Improved intelligence gathering, risk management and Joint Customs Operations;
- Enhanced cooperation among EU agencies and with major source and transit countries;
- Strengthened sanctions;
- Sharing of expertise and best practises;
- Endorsement of the WHO Framework Convention on Tobacco Control (FCTC) Protocol to eliminate illicit trade in tobacco products (the 'Protocol'); and
- The adoption of the Tobacco Products Directive.

1.2.5 THE FCTC PROTOCOL

The global scope and multifaceted nature of the illicit tobacco trade requires a coordinated international response and improved global regulation of the legal tobacco

⁴ European Commission. Stepping up the fight against cigarette smuggling and other forms of illicit trade in tobacco products – A Comprehensive EU Strategy. Brussels; 2013 Jun.

trade. The illicit tobacco trade is regulated by Article 15 of the World Health Organization (WHO) FCTC and by the Protocol, which has been negotiated as a supplementary treaty to the World Health Organisation’s (WHO) Framework Convention on Tobacco Control. The Protocol, adopted at the fifth conference of the parties in November 2012, will come into force on the 90th day following the date of the 40th ratification of the protocol. As depicted in Figure 2 below, the Protocol requires secure marking and tracking and tracing of tobacco products.

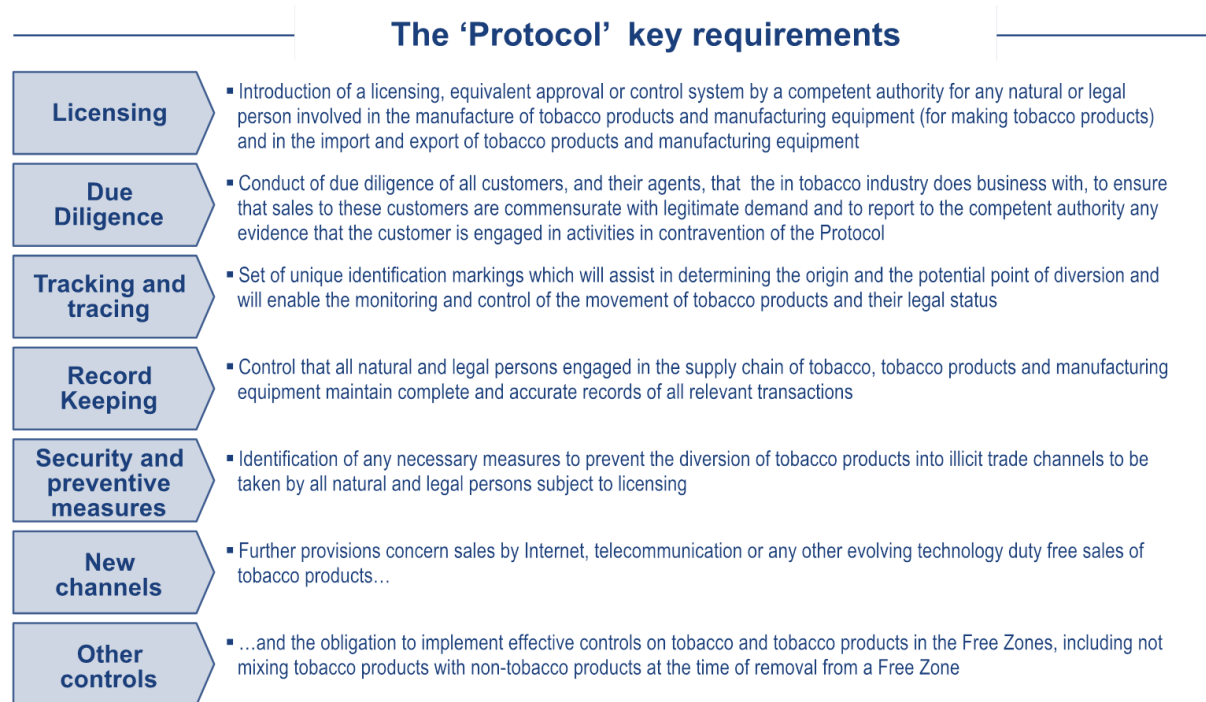


Figure 3 – The Protocol to Eliminate Illicit Trade in Tobacco Products was adopted by the Conference of the Parties to the WHO Framework Convention on Tobacco Control (FCTC)

One of the core measures of the Protocol is the tracking and tracing regime (article 8). According to this article, each Party shall require that unique, secure and non-removable identification markings, such as codes or stamps, are affixed to or form part of all unit packets, packages and any outside packaging of cigarettes within a period of five years, and other tobacco products within a period of ten years of entry into force of the Protocol.

1.2.6 EUROPEAN TOBACCO PRODUCTS DIRECTIVE (TPD)

An EU tracking and tracing system of tobacco products and for security features is foreseen in Article 15 and 16 of the Tobacco Products Directive 2014/40/EU of 3 April 2014. The rationale for the tracking and tracing system in the Tobacco Products Directive 2014/40/EU is that considerable volumes of illicit products, which do not comply with the requirements laid down in Directive 2001/37/EC, enter the market and that such products undermine the free circulation of compliant products and the protection provided for by tobacco control legislation, explained in the recitals 29-31 of the Directive. The main department within the European Commission services involved in the follow-up of Article 15 and 16 of the TPD is the Directorate General for Health and Consumers (DG SANCO), whose task it is to guarantee the free movements of compliant tobacco products and to ensure a high level of public health in the EU.

1.2.7 MULTIPLE STAKEHOLDER REQUIREMENTS

The traceability and security feature system for tobacco products will be beneficial to a number of stakeholders. The Project required consideration of the priorities and potential functional requirements for each stakeholder. A summary of key stakeholders in relation to the TPD is depicted in the table below.

Table 2 - Stakeholder mapping to TPD Article 15 & 16

Stakeholder	Article 15/16 Benefit
Law Enforcement (Police, Customs, Tax and Public Health)	<ul style="list-style-type: none"> ▪ All products marked with a unique identifier. In combination with a database this provides information from the manufacture to the first retail outlet which is accessible for law enforcement officials see Article 15 (8) ▪ Unique identifiers are indelible and security features are tamper proof ▪ All products intended for the EU market carry tamper-proof security feature composed of visible and invisible elements ▪ Information is stored in a database which is accessible for law enforcement officials see Article 15 (8)
OLAF	<ul style="list-style-type: none"> ▪ Economic operators involved in the trade of tobacco products, from the manufacturer to the last economic operator before the first retail outlet, record the entry of all unit packets into their possession ▪ Information on the product through the supply chain is stored in a database which is accessible for OLAF officials see Article 15 (8)
UNODC	<ul style="list-style-type: none"> ▪ Depending on administrative cooperation arrangements, the supply chain data could indirectly be of use to UNODC and WCO efforts (with the possibility to provide this information through a request process agreed by the EU Commission and Member States. ▪ All products intended for domestic market carry tamper-proof security feature composed of visible and invisible elements
WCO	
WHO FCTC Secretariat	<ul style="list-style-type: none"> ▪ Provide a foundation for EU Member States to participate in the FCTC global information sharing focal point. ▪ Traceability of tobacco products to combat illicit tobacco products
DG SANCO	<ul style="list-style-type: none"> ▪ All products intended for domestic market carry tamper-proof security feature composed of visible and invisible elements to guarantee regulated tobacco products. ▪ Traceability of tobacco products to combat non-conformant and/ or illicit tobacco products
DG TAXUD	<ul style="list-style-type: none"> ▪ Economic operators involved in the trade of tobacco products, from the manufacturer to the last economic operator before the first retail outlet, record the entry of all unit packets into their possession. ▪ Information on the product through the supply chain is stored in a database which is accessible for DG TAXUD officials and the customs administrations of the Member States in the context of the Common Risk Management Framework - see Article 15 (8)".
Consumers	<ul style="list-style-type: none"> ▪ All products intended for domestic market carry tamper-proof security feature composed of visible and invisible elements
Industry	<ul style="list-style-type: none"> ▪ All products intended for domestic market carry tamper-proof security feature composed of visible and invisible elements

1.2.8 TOBACCO SUPPLY CHAINS IN THE EUROPEAN UNION

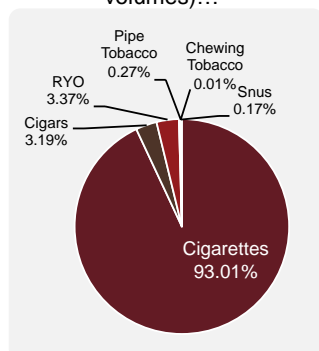
The EU market for tobacco products comprises mostly the sale of cigarettes (over 90%) that are produced on +/- 745 production lines within the Union. The four largest tobacco

manufacturers dominate this market: Philip Morris, Japan Tobacco, British American Tobacco and Imperial Tobacco. Currently, most of this EU production is subject to a tax stamp or fiscal mark, which shares certain attributes to the security feature as envisaged in the TPD.

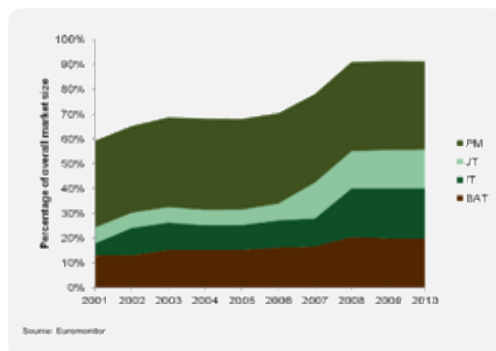
Number of Players & Items in the EU Market...



Cigarettes account for majority of tobacco (estimated retail unit volumes)...



"Big 4" tobacco manufacturers have more than 85% of the overall EU tobacco market...



Majority of EU Tobacco Products subject to Tax Stamp / Fiscal Marking...

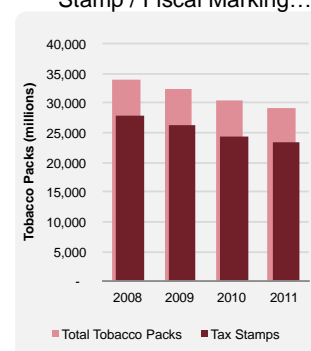
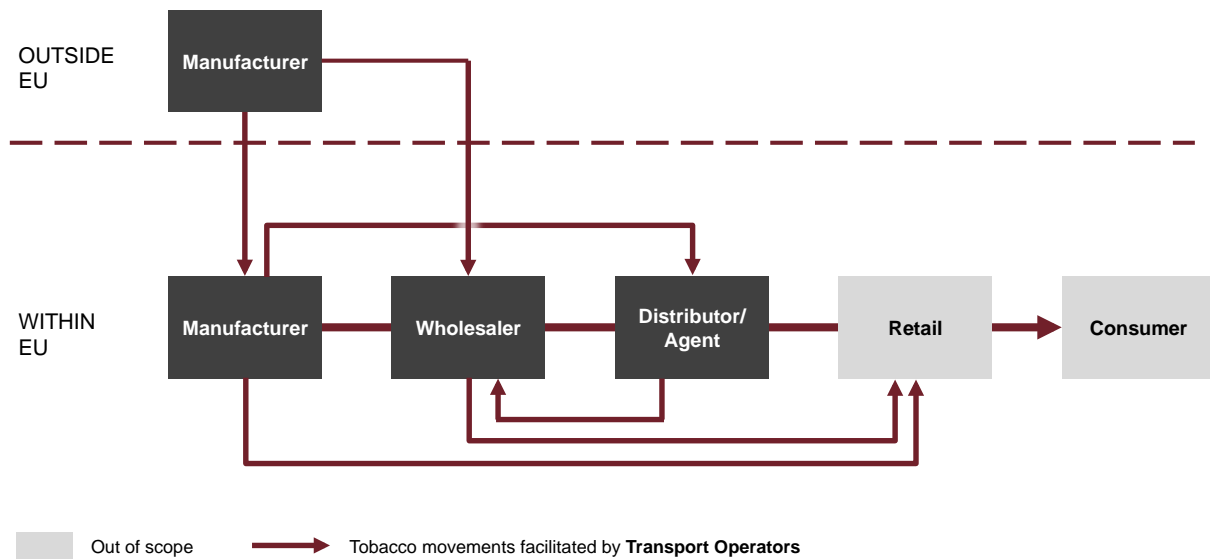


Figure 4 - Number of Tobacco Companies and Cigarettes in the European Union Market

The TPD indicates that the traceability requirements must be met by all tobacco products "which have either been manufactured in the EU or are imported into the EU to be placed on the EU market." Furthermore, all units of tobacco products placed on the EU market must carry a security feature. Reference is made to the responsibilities for tracking the movement of tobacco products from the manufacturer until the last economic operator before the first retail outlet. The following supply chain illustration shows the scope within the context of the tobacco supply, manufacture and distribution chain.



The tobacco growers, processors, and retailers are considered out of the scope of the traceability solution. It should be noted that although the consumer and retailer are shown as out of scope in terms of the traceability solution, they are both seen as stakeholders and users of the security feature. It is envisaged the consumer will be the primary user of the overt (visible) security feature to be applied to tobacco packs to provide a mechanism that aids authentication that the product is legitimate. The number of possible combinations of supply flows applicable to tobacco supply chains is diverse and also includes shipping exceptions (repacking, damaged goods, returns, etc.). Various tobacco distribution chain flows are possible, and an illustration of these is included below.



The EU Tobacco distribution chain is very broad. In 2013 it is estimated approximately 230 Manufacturers operated some 332 tobacco manufacturing facilities within the EU⁵. These products are distributed to the retail environment through a network of 2,450 wholesalers and distributors⁶. In total, just under 1 million point of sale outlets stock and retail tobacco products. In addition, tobacco products are also made available through an estimated network of 671,000 vending machines.

1.2.9 THE CROSS-BORDER MOVEMENTS OF TOBACCO PRODUCTS

The tobacco traceability solution will also need to consider product movements into, within and out of the EU. The matrix below illustrates the main movement types: The vertical axis plots the origin of the goods, while the horizontal axis plots the destination of the goods.

Therefore, any traceability solution needs to consider:

- **Internal Market:** The method tobacco products produced within the EU community are marked with unique identifiers and security features and tracked within the Member States;
- **Imports:** The marking of tobacco products manufactured outside of the EU with unique identifiers for traceability and security features for authentication purposes, prior to the goods being made available on the internal market. Further, there may be consideration as to whether products are marked

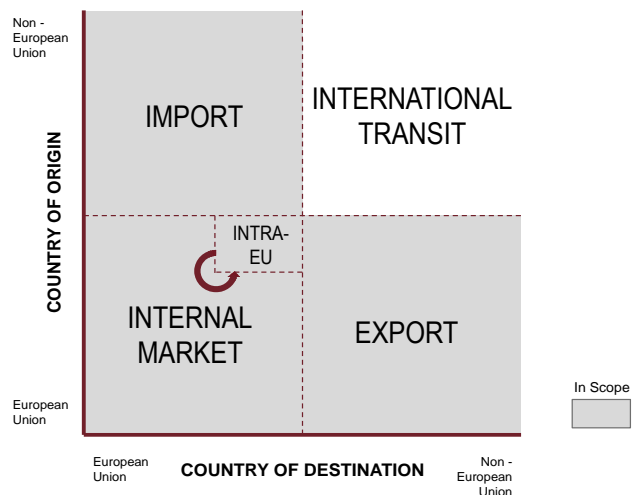


Figure 5 - Nature of Tobacco Trade Flows from an EU Perspective

⁵ See 11.4.2.2.1 of the report for estimate of number of operating tobacco manufacturers in the EU.

⁶ Eurostat (2012)

at the time of manufacture in the foreign country, or marked at the time of import (or both);

- **Exports:** The application of unique identifiers for traceability purposes for goods manufactured in the EU, where those tobacco products are intended for placement on a foreign market outside of the EU; and
- **Intra-EU:** Where tobacco products originating in one Member State are transported for placement on the internal market in another Member State.

International transit is considered out of scope both in terms of traceability and for application of security features, as these goods are neither manufactured in the EU, nor intended for placement on the EU internal market.

1.2.10 INTRA-EU TRADE

The value of tobacco products movements between Member States within the EU is substantially larger than the flows of imports and exports with non-EU trading partners. For 2010, the overall value of cigarettes traded between EU Member States was € 6.5 billion, representing ~5% of all cigarettes consumed within the EU. The trend shows that the value of tobacco products being transited within the community has been increasing over the past 10 years.

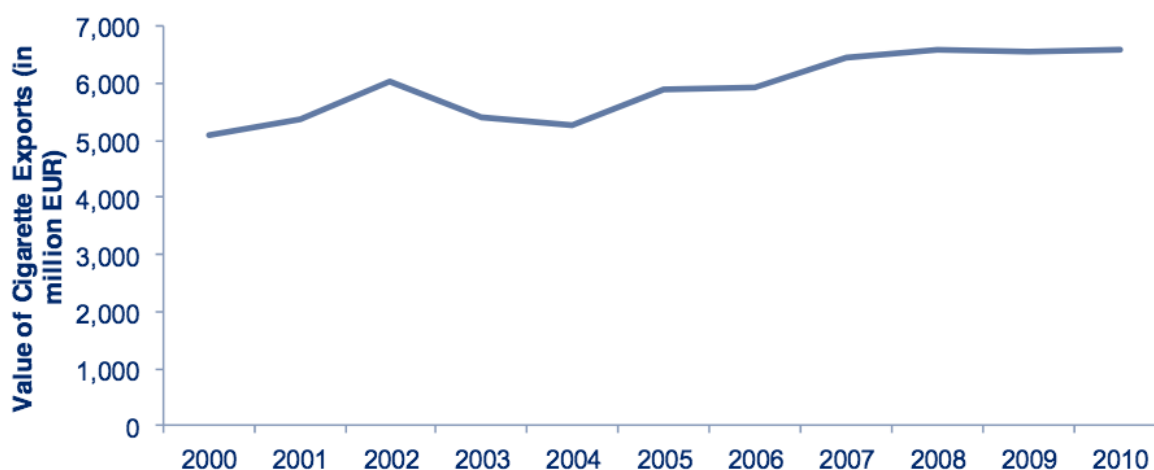


Figure 6 - Value of intra-EU trade of cigarettes (2000-2010)⁷

1.3 CONSOLIDATED PROBLEM STATEMENT

Illicit and unregulated tobacco products can harm the public and increase tobacco consumption, undermining the objectives of EU Health Policies. These non-conformant tobacco products do not adhere to manufacture, formulation, packaging and pricing requirements intended to reduce harm and curb tobacco consumption. Without adequate controls in place, these illicit products are able to enter and circulate in the EU internal market to be consumed by the public.

⁷ Matrix Report, 2013. Note: Data are not available for all of the 2000-2010 period for Malta, Slovakia, Slovenia, Cyprus, Hungary, Romania and Poland. Figures are based on export declarations (typically pre-tax values)

To support the tobacco control policies of the Member States a solution is required that will support Member States in determining the market legitimacy of tobacco products, in order to protect the internal market from non-conformant products. Furthermore, such a solution will help authorities to determine compliance with customs and tax obligations. Consumers should be provided a mechanism to authenticate that tobacco products available for purchase are legitimate.

All of the factors, as summarised in the above section, were taken into consideration when conducting the project analyses. Key functions and desired outcomes were distilled into two sets of distinct critical success criteria. The tables below depict these two sets of criteria with a reference to the applicable reference points within the TPD.

Table 3: Critical Success Factors for Traceability:

1	Ensure each pack is marked with a unique identifier; (Article 15, §1)
2	Provide an accurate mechanism for recording the movement (tracking) of tobacco products from the point of manufacture to the last economic operator before retail; (Article 15, §5)
3	Support the concept of aggregation, wherein the items within a container (carton, master case, pallet etc.) are recorded, and a unique identifier is then assigned to the container and used as the basis to record the movement of the container (with its contents) through the distribution chain. This parent-child relationship can record the hierarchy between packs and cartons, cartons and master cases, and master cases and pallets; (Article 15, §5)
4	Store data independently (not by the tobacco industry); (Article 15, §8 and recital 31)
5	Ensure that the systems used for the unique identifier and the related functions are fully compatible with each other across the European Union; (Article 15, §11b)
6	Protect confidentiality and safeguard that decoding and full access to the data storage facilities is limited to authorised authorities and only exceptionally in duly justified cases to the tobacco industry under restrictive conditions; (article 15, §8)
7	As far as possible, be compatible with current tobacco production, packaging and the trade environment to minimise the impact on tobacco production taking into consideration production speeds, equipment, etc. (internal market proportionality obligations);
8	Uphold respect for data protection as specified in the EU legal framework (Directive 95/46/EC); (Article 15, §10)
9	Be resistant to manipulation. This includes physical measures such as providing that marks are irremovable and indelible, but also solution design considerations such as non-predictability of unique identifier codes, traceability data reconciliation against other data sources, safeguards against traceability being accessed / used by unauthorised parties; (Article 15, §1)
10	Enable Member States and EU authorities to monitor and survey the market as per respective mandates; (general aim of Article 15 and recital 29)
11	As far as possible, utilise solution components currently being used in a commercial supply chain environment and avoid unnecessary burden for business and/or authorities (Impact assessment considerations).

Table 4: Critical Success Factors for Security Features

1	Provide a reliable mechanism to authenticate the legitimacy of a tobacco product; (Article 16, §1)
2	Have overt elements which provide the modicum of authentication by the consumer without requiring specialised equipment / devices; (Article 16, §1 and impact assessment considerations)
3	Must be tamper proof and irremovable; (Article 16, §1)
4	Ensure that covert elements are accessible by authorised persons and protect commercially sensitive data, if necessary; (article 16, §1 and impact assessment considerations)
5	Provide court-admissible forensic evidence of security feature authentication;
6	As far as possible, be compatible with the current tobacco production, packaging trade environment and existing tax regimes and avoid unnecessary burden for business and/or authorities (internal market proportionality obligations).

1.4 DEVELOPING A MODEL FOR ASSESSMENT

Task 1 and 2 required the identification and mapping of both tracking and tracing solutions, as well as security feature solutions, suitable for tobacco products, organised by country or industry level with a particular emphasis on systems which are currently operating around the world⁸. The Problem Statement, as described above, serves as the primary baseline, which was incorporated into a model for mapping solutions available on the market. This model was built as a configurable Assessment Matrix tool. The model facilitated the Project analyses and allowed for the visual mapping of solutions based on their “fit for purpose” across two dimensions: Functional Scope & Maturity and Breadth of Experience:

- **Functional Scope & Maturity:** The degree to which the proposed solution offering provides the necessary functional components for a traceability solution suitable for tobacco products, the understanding of traceability requirements, and fit to the problem statement.
- **Breadth of Experience:** Consideration of existing implementations and experience implementing, operating and maintain required solution components.

This matrix approach was created using industry best practices in technology evaluation. Although the model developed for the Project is bespoke, it can be compared to the Gartner Magic Quadrant™ approach to technology evaluation that also provides a visual mapping format across two dimensions, as considered in academic literature⁹. In the model developed for the Project, each dimension includes multiple criteria and sub-criteria that serve to define the requirements at a high level of specificity. All criteria and sub-criteria contained in the model can be scored and weighted according to the overall parameters of the evaluation and composite scores can be generated. The following figure depicts the criteria for track and trace evaluation as contained in the tool with respect to the two dimensions and evaluation criteria.

⁸ Call for Tender: 2013/EAHC/HEALTH/11, “Analysis and Feasibility assessment regarding EU systems for tracking and tracing of tobacco products and for security features”, Specifications Attached to the Invitation to Tender, § 3.3

⁹ Neil Pollock et Robin Williams, «The sociology of a market analysis tool: How industry analysts sort vendors and organize markets», *Information and Organization*, 2009, vol. 19, no 2, p. 129–151.

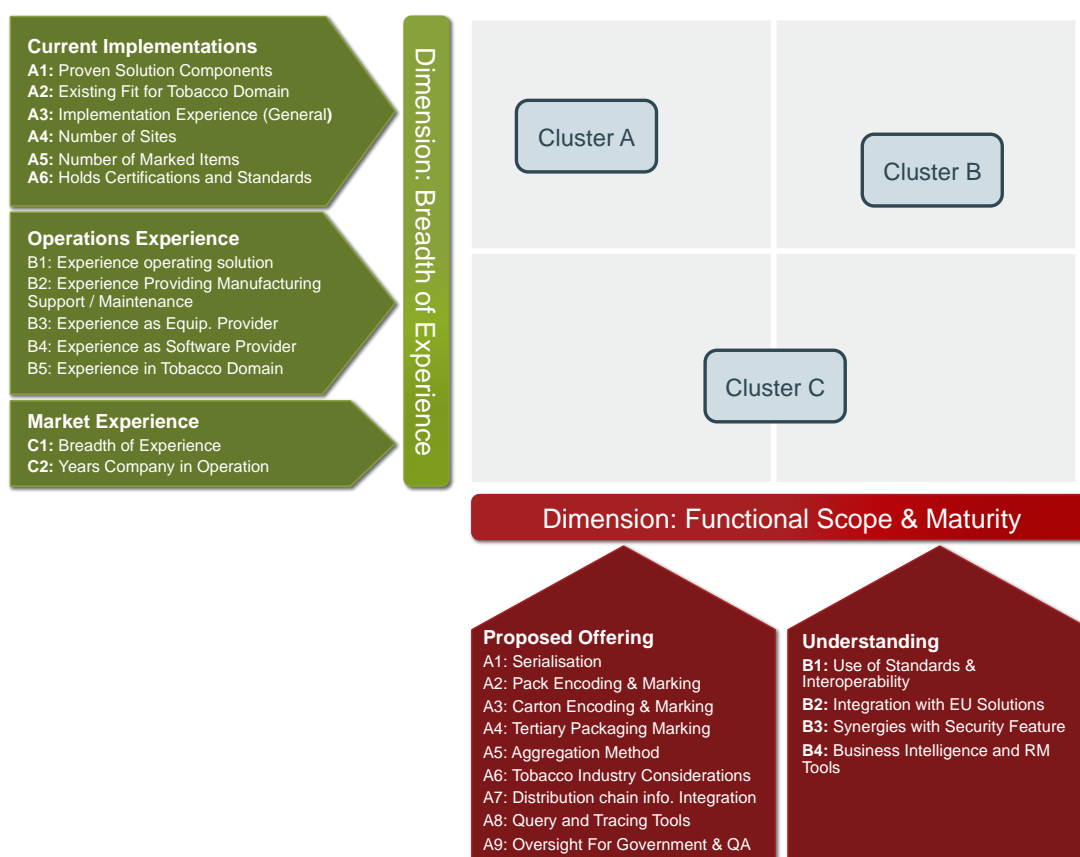


Figure 7 - Assessment Matrix Analysis Dimensions & Criteria (Traceability)

The initial evaluation of solutions and technologies was performed, made available and discussed with the EU Commission project team. This further supported the ability to validate and gather additional information (e.g. site visits) that confirmed the findings for the Final Report.

1.5 SUMMARY OF KEY FINDINGS AND DELIVERABLES

The following general findings can be attributed to the overall Project with specific details highlighted further in this section and set out in detail subsequently in this report:

- Implementation of tobacco implementation of traceability is feasible both technically and from a competitive market perspective (see Market Assessment);
- Traceability is a growing trend globally and is being applied across multiple industries (see Case Studies);
- The needs of varied stakeholders are not mutually exclusive and multiple parties can benefit from secure traceability, e.g., public health, law enforcement, revenue, consumers;
- There is no "one size fits all" solution; traceability can be achieved via multiple approaches with respect to technology, solution architecture and governance (see Four Options for Traceability and Security Features);
- Global standards for communication, product and supplier identification are already prevalent in today's tobacco supply chains, and this usage will enable traceability (see 4.3);

- Independent data storage is not only feasible, but the estimates of data storage requirements show this to be manageable (and not as large as originally envisaged); and,
- The accumulative estimated benefits of tobacco traceability outweigh the costs to industry and government (see Cost Benefit Analysis).

1.5.1 MARKET ASSESSMENT

1.5.1.1 TRACK AND TRACE

The primary intent of the Market Assessment was to analyse the market of potential technologies and solution providers for tobacco traceability. The results indicate that not only is the implementation of tobacco traceability feasible, but there is already a robust and growing market of potential suppliers with differentiated offerings. The assessment further indicated that there are emerging technologies and solutions that whilst still unproven in the field, are nevertheless also potential options for tobacco traceability. Track and trace is a relatively new and emerging practice in supply chains (particularly with respect to product-level track and trace) and there is a lot of marketing activity, but far less proven implementations with regard to traceability at the product unit level. Most of the traceability occurring in other market areas are applied at packaging [one or two levels up from product unit level (such as pack level)] and consist of tracking of master cases, pallets and conveyances, or consider traceability of an item to the point of manufacture only, without tracking subsequent movement events.

In the tobacco domain, the Project identified a significant number of solution providers advertising leading track and trace technologies and capabilities, however for most, actual implementation experience proved to be limited or non-existent.

Solution mapping displayed a wide spread of actors on the Assessment Matrix, both in terms of a functional scope & maturity and breadth of experience. Of the 44 organisations that completed the survey, a total of **32**¹⁰ indicated they provided a track and trace solution suitable for tobacco products. The diagram below illustrates the solutions which are clustered across four main categories of solutions identified during the Assessment, including:

- **Track and Trace Building Blocks** -- part of a solution exists but would need to be combined with others to deliver on a complete solution. This also includes solutions that are very basic and would require significant enhancement.
- **Track and Trace Base Solution** -- most elements required for a traceability solution exist but as a standalone solution, does not meet all the identified

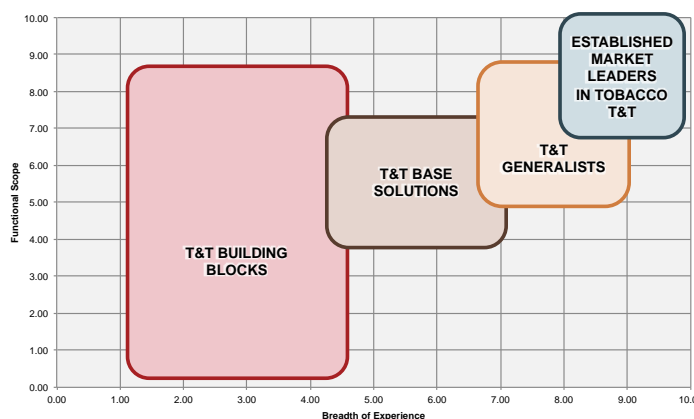


Figure 8 Overview of Traceability Solution Marketplace

¹⁰ Four organisations responded as providers of a track and trace solution that, in effect, was the same underlying track and trace solution being promoted by the tobacco industry using the Codentify code assignment module under the umbrella of the Digital Coding and Tracking Association (DCTA).

requirements for the tobacco domain [includes a number of solutions from other sectors (e.g., pharma, FMCG, etc.)].

- **Trace and Trace Generalists** – Competent solutions that operate in other industries but without experience in the tobacco domain and specific attributes related therein (e.g., aggregation, supply chain anomaly reporting). Therefore, further solution elements / functionality may be required to meet the requirements for an EU Tobacco traceability solution¹¹.
- **Established Market Leaders in Tobacco Traceability** – Solutions with existing implementations and incorporate considerable experience with specifics related to tobacco manufacturing (e.g., environment, equipment etc.). These are mature solutions that today meet the requirements for traceability as per the Problem Statement.

The “Breadth of Experience” dimension within the assessment matrix includes several criteria establishing that the solution has actually been implemented and operational. The graph alongside reveals the considerable disparity with respect to implementation experience amongst the participating solution providers. The graph shows the number of items per month controlled by the traceability solution, ranked from highest to lowest, with the largest two solution providers highlighted.

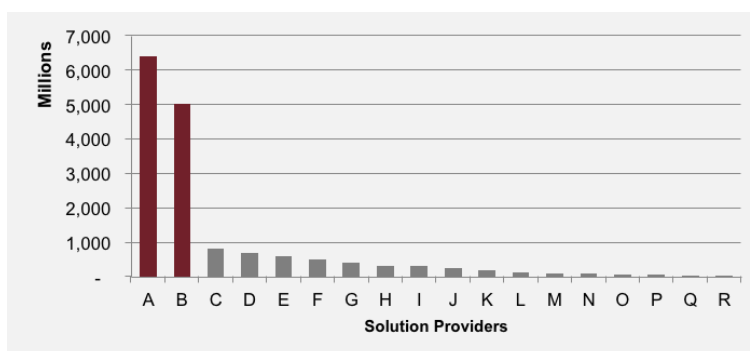


Figure 9 – Number of Items marked per year- variety in scale of current operations amongst solution providers

1.5.1.2 SECURITY FEATURES

Of the 44 organisations participating in the survey, a total of 38 organisations indicated they were a provider of security features suitable for tobacco products, and were included in the Security Feature Assessment Matrix analysis. This included a broad spectrum of security feature providers, including several established operators in this segment, a mix of new and emerging technology solution providers and organisations affiliated with the tobacco industry. The preliminary mapping of the three main categories of security feature providers on the Assessment Matrix is presented in the figure below.

Four organisations responded as security solutions providers that use “digital” serialisation¹² that is the same underlying track and trace solution being promoted by the

¹¹ The assessment of these solutions identified some shortfalls in described functions against the full evaluation criteria. However, the effort estimate for these solutions to be upgraded to provide the full required functionality cannot be assessed without further examination of each solution. For example – a traceability solution currently supporting production line speeds of only 400 items per minute (suitable in the context of pharma) could potentially be upgraded to operate a 1,000 packs per minute (required for a high speed tobacco line) easily, or might require considerable redevelopment effort to overcome the potential technical hurdles posed by these operating speeds. This upgrade effort could therefore differ significantly - with assessment of such not forming part of this study.

¹² Serialisation ensures each and every item is marked with a unique identifier. This provides the basis to monitor and record the existence, location, and associated events of that item from the moment the mark is applied, potentially through its use / consumption lifecycle.

tobacco industry via the DCTA. All four of these organisations promoted serialisation through the use of the Codentify application and proposed this as the security feature, which is discussed further below. Three distinct clusters emerged in the analysis of security feature providers:

- Niche Security Feature Providers** -- providers that are specialised and offer only partial security feature offering (such as a forensic marker suitable as a covert element only). This cluster also includes four organisations that provided incomplete and/or unclear responses or cited non-disclosure agreements in their survey responses. The assessment criteria were applied to the provided responses and in these cases resulted in lower ratings.

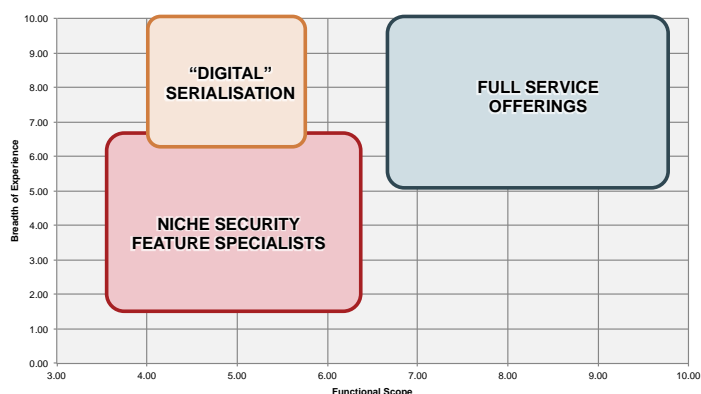


Figure 10 - Overview of Security Feature Marketplace

- Digital Serialisation Being Offered as an Overt Feature** -- The top left of the quadrant contains a cluster of solutions that all share a common element: the claim that an alphanumeric code applied to the tobacco packs provides an overt security feature for authentication. These claims fall short, as the proposed serialisation technique by itself fails to meet requirements of an overt security feature.
- Full Service Offerings** -- The analysis showed a strong cluster comprising more than 10 security feature solution providers in the top right quadrant. These organisations showed a competent understanding of security features with overt, covert and forensic elements. These organisations also demonstrated strong experience providing security features for use on currency, for brand protection purposes and on tax / fiscal markings.

Because there are a considerable number of providers overall, particularly in the far right cluster, we anticipate little difficulty sourcing capable providers for security features meeting the identified critical success factors suitable for tobacco products.

The solution provider survey responses showed there is a strong reference to apply security elements by means of a label to tobacco products. In fact, the label was put forward as a proposed application method by all but one of the respondents that offered overt, covert and forensic security features (in addition serialisation). It is anticipated this is primarily because of the nature of the security feature industry and that a secure label allows:

- A far greater range of security elements and techniques that may be incorporated into the security feature as the security feature provider has control over the substrate where additional security elements can be embedded (e.g. security fibres, taggants, nano-particles and/or RFID chips) as well as the security elements applied / printed.
- Production of the security feature can take place within a secure and controlled facility where access is restricted. This would be preferable to having the security features applied in uncontrolled commercial environments (e.g. commercial printers preparing tobacco packaging materials) or within the tobacco manufacturing facility itself; and

- A central controlled location where the techniques and security elements of the security feature can be secured, controlled, adapted and upgraded over time to address evolving counterfeiting attempts and threats.

1.5.1.3 WIDE SCOPE AND VARIETY OF OVERT, COVERT AND FORENSIC SECURITY FEATURES

The industry agreed practice in the domain of security features and authentication advocates that a security package should comprise layering overt, covert (invisible) and forensic security features.¹³ By combining a package of security features, access can be controlled for different inspectors (e.g. consumer, distribution chain operators, enforcement authorities) and also increase security so that no one party has access to all the elements.¹⁴ It is for this reason that covert is sometimes further divided to include "semi-covert". Like covert, "semi-covert" requires a device for authentication. Authentication devices range from simple to sophisticated. Simple devices include UV lights, polarising filters or others types suitable for various users (e.g. distribution chain operators). Other covert features must be verified using more sophisticated device typically reserved for Government authorities.

The project reviewed over 40 categories of overt, covert and forensic security technology types. Overt elements were assessed in terms of perceived defence against imitation, affordability, ease of training to use and suitability for tobacco control. In addition to these criteria, covert elements were rated against suitability for use by EU and Member State officials (use case of authenticating the covert feature while in the field) and the complexity and prevalence of devices that can be used to authenticate the covert security element. To complete the review, the project assessed several fingerprinting technologies that rely on identifying and recording certain chaometric events that cannot be replicated. This emerging field offers several interesting developments for covert security features.

This review showed there were a number of authentication technologies available suitable for the tobacco domain that could be combined to create a security feature with overt, covert and forensic elements.

In addition to the package of security feature elements, the method in which these security features can be applied to each unit of tobacco product was also considered and these included:

1. Incorporating the security feature as part of the production of the packaging material itself.
2. Including the security feature in a specific element of the packaging that can be controlled (e.g. tear tape).
3. Printing the security feature using security inks directly onto the product.
4. Providing the security feature as self-contained security package as a label, film or stamp.
5. Security feature combined with fingerprinting of unique material properties of the package.

In preparing the four options for security features for further assessment and the cost benefit analysis, the choice of providing the security feature as a label / stamp (method

¹³ NASPO, 2009. How to Select a Security Feature: A structured Guide for the selection of a Security Technology for Documents and Items of Value.

¹⁴ ISO 12931: 2012(E)

4), with the further consideration of using fingerprinting techniques (method 5), was used for the following reasons:

- The limited security of using commercial printing techniques was considered a weakness for production of a security feature intended to aid efforts to reduce counterfeit or falsified products;
- Using clear wrap or tear tape packaging elements did not readily meet the requirements for an irremovable security feature; and
- The secure label / stamp provided additional implementation flexibility, choice of security elements and compatibility with both high speed and low volume tobacco production, as well as automated and manual packaging method.

1.5.2 STANDARDS FOR TRACEABILITY

The use of standards, such as those promoted by GS1¹⁵, has increased in recent years with advances in supply chain logistics and related efficiencies. Although there are other existing standards in regards to track and trace, GS1 standards are clearly the most commonly adopted by supply chain actors across industries, and certainly within the tobacco supply chains reviewed as part of this report. EPCIS is an open standard from GS1 that defines interfaces enabling logistics events to be captured and queried as they occur in the supply chain. GS1's EPCIS provides a standard for enabling the **"Who"**, **"What"**, **"Where"**, **"When"**, and **"Why"** of events occurring in any supply chain to be exchanged, safely and securely. That includes information such as the time, location, disposition and business step of each event that occurs during the life of an item in the supply chain. The following diagram illustrates the main attributes of GS1 standards and their respective functions with respect to track and trace.

STANDARDS AT THE CORE OF TRACK-AND-TRACE			
	EXAMPLE	STANDARD	
EPCIS	WHO	Ship-From, Ship-To, Buyer, Seller	GLN
	WHAT	Products, Logistics Units, Assets, Relationships	GTIN, SSCC, GRAI, GIAI, GSRN
	WHERE	Postal Locations, Warehouses, Floors, Rooms	GLN
	WHEN	Time and Date	
	WHY	Commissioning, Packing, Shipping, Receiving, Dispensing	Business Step

Figure 11 - GS1 Standards at the core of Track and Trace

Without such a standard, every company would likely define their own data models and semantics differently for logistics events as products move throughout the supply chain. Although the EPCIS uses the Electronic Product Code (EPC) as identification schema, it does not apply any restrictions and can work with any ID schema, e.g. EAN-13 or 2D codes. Extensions of the event format are possible, e.g., new data fields in the event message or new event types enable the adaptation of EPCIS to a particular domain.

¹⁵ GS1 is an international not-for-profit association with Member Organisations in over 100 countries. The organisation develops and maintains standards for supply and demand chains globally across multiple sectors. GS1's website: <http://gs1.org>

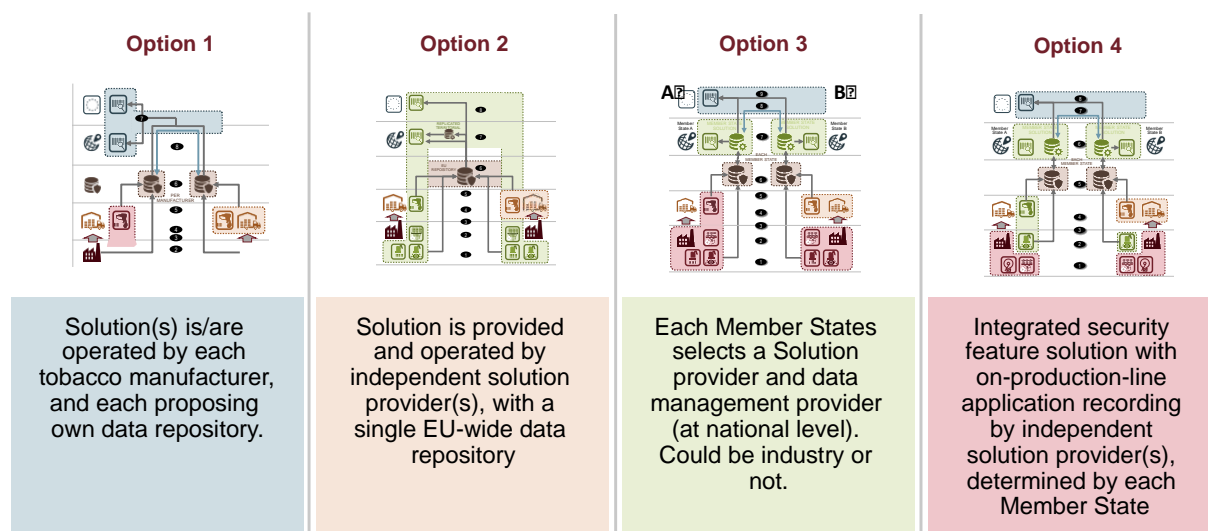
1.5.3 FOUR OPTIONS FOR TOBACCO TRACEABILITY

The Tender specification required that four distinct options be first identified and then later assessed. Thus, four distinct architectures have been established. This approach has allowed for virtually an all-encompassing review of potential solution combinations and has facilitated the analyses in terms of functional aspects of each solution, related costs, governance models and impact on key stakeholders. Each of the four options meet the overall requirements as set out in the Problem Statement, with differences in terms of distribution of roles and responsibilities, administrative burdens as well as implementation and operational risks. The development of four proposed solution options considered several factors:

- The balance of providing effective control and oversight through the traceability solution for the purposes of tobacco control, against consideration to moderate costs and minimise the impact of the solution on tobacco manufacturers and distribution chain operators;
- The allocation of responsibility for the different track and trace solution components between Member States and the EU (community wide functions);
- The potential scope and synergies resulting from system integration with existing EU tax administrations, fiscal stamps and marks, trade control and enforcement systems;
- Efficiency of the solution, together with the suitability of each track and trace solution against requirements to support a variety of manufacturers (with varying degrees of automation), importers, distributors and typical distribution operators in the tobacco domain.

Several of the solution-critical success factors and requirements potentially conflict with one another, for example, mechanisms to create a solution that resists manipulation (critical success factor 10), may have additional impact on tobacco manufacturers (critical success factor 8). Therefore, the following four options address a range of solution architectures, each attempting to provide an optimal compromise to balance different perspectives or stakeholder needs.

Each of the four options contains considerable detail that is specified in the Report, however the diagram below provides a simplified summary of each.



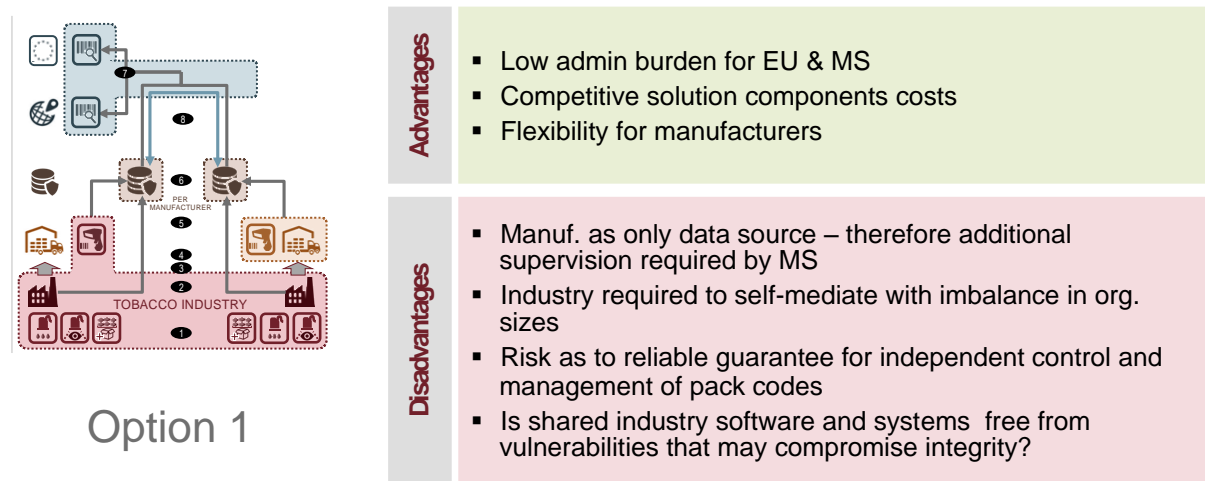
1.5.3.1 TOBACCO TRACEABILITY: OPTION 1

Option 1 is an industry-operated and led tobacco traceability solution. Under this option: the EU Commission prescribes the standards but the tobacco manufacturers operate the solution (except for the submission of data storage to an independent repository, which needs to be done by an independent data storage provider as per the TPD).

KEY PRINCIPLES

- EU Commission establishes the minimum data required on tobacco packaging and a mechanism for both EU and Member States authorities to have access to this data. The EU Commission prescribes standards and the format of how manufacturers and distribution chain operators submit tobacco event information to independent data management providers.
- Tobacco industry is responsible for operating all aspects of the tobacco traceability solution within their sites, making the required minimum data accessible to Member States and EU authorities. Generation, application and recording of the unique identifier on tobacco units, including aggregation and shipment events, is performed by the manufacturer using their own and/or industry-developed solution.
- Distribution chain operators record and submit tobacco tracking events either using their own systems (using EU prescribed form for data exchange) or using a solution / device provided by the tobacco manufacturers.
- Data storage is provided by 3rd party data storage providers (independent of manufacturers and distributors) with controls in place to guard against data losses or amendment by unauthorised parties.

ANALYSIS



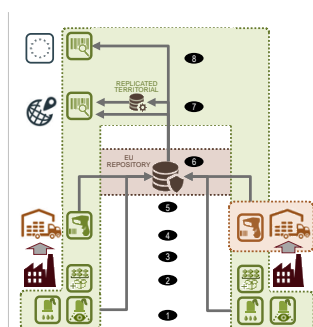
1.5.3.2 TOBACCO TRACEABILITY: OPTION 2

Option 2 involves the EU Commission prescribing the standards and appointing **one or more solution providers** as an independent 3rd party to implement and manage a Community-wide tobacco traceability solution.

KEY PRINCIPLES

- A Single Tobacco Traceability solution deployed as a standard harmonised EU Community system; Member States enforce and ensure the solution is implemented by all tobacco manufacturers and distribution operators in their jurisdiction.
- The solution may be operated **by one or more solution providers** that are independent of the tobacco industry. The solution provider(s) implement technology components for serialisation of tobacco items, aggregation and submission of traceability data to a single EU data repository for storing traceability events. EU Standards ensure interoperability of the solution components.
- EU Community system provides standard interfaces for distribution chain operators with automated systems to submit traceability data (receipts and dispatches) to the EU event repository. Alternatively, the provider(s) offer a stand-alone solution component for non-automated / SME distribution chain operators to record the receipt and dispatch of tobacco products, which is also uploaded to the central EU event repository.
- EU agencies and Member State authorities have access to a central EU event repository for monitoring and analysing tobacco traceability data. A further option for Member States may be the replication of this data to own data stores to support national monitoring activities.

ANALYSIS



Option 2

Advantages

- Segregation reduces fraud risk
- Scale advantages
- Single location: -Simplified admin, supports complex analysis & improves oversight
- Interoperability creates competitive bid environment

Disadvantages

- Prescribed components reduce flexibility for manufacturers
- Additional mitigation required to not cause production downtime by 3rd party.

1.5.3.3 TOBACCO TRACEABILITY: OPTION 3

Option 3 is a blended solution where the EU Commission mandates minimum standards (for interoperability) and each Member State establishes their own solution requirements, and chooses to appoint either the Tobacco Manufacturer or an independent Solution Provider to implement the system.

KEY PRINCIPLES

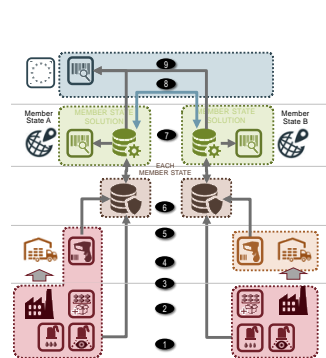
- Option 3 considers a solution where Member States prescribe the tobacco traceability solution, whether operated by industry or a solution provider independent of industry and that applies to all tobacco manufacturing and tobacco movements and sales within the Member State.
- The EU Commission mandates the minimum data to be recorded, interoperability standards and provides a means for EU agencies and other Member States to access a Member State's tobacco traceability data under controlled circumstances

to support risk management, enforcement and investigation activities within the EU community.

- Each Member State appoints a data management service provider as the repository for national tobacco traceability data.
- EU access to data will be limited to providing a mechanism for data queries to operate across Member State data repositories. Detailed data analysis will be based on requests to the Member State for access to relevant data.
- Distribution chain operators (DCOs) operating within a particular Member State record distribution chain events either using their own systems then submit to the Member State repository using prescribed industry data exchange standards, or use a solution offered by either the tobacco industry or independent solution provider, as applicable for that Member State.

The report considers two variations for the third option: option 3a considers the scenario that different Member States may appoint tobacco manufacturers to operate the tobacco traceability solution; option 3b considers each Member State appointing an independent solution provider.

ANALYSIS



Option 3

Advantages	<ul style="list-style-type: none"> ▪ Autonomy and choice for MS ▪ Increased opportunity for smaller solution providers ▪ Member States flexibility in level of independence & control
Disadvantages	<ul style="list-style-type: none"> ▪ Fragmentation increases complexity and cost ▪ Hinders coherent tobacco control strategy ▪ Depending on blend - option 1 and Option 2 disadvantages <p style="text-align: center;">Solution by Member State</p> <ul style="list-style-type: none"> ▪ Higher implementation and change management effort ▪ Integration of Member State level data sources required for EU-level oversight and tools for EU Agencies. ▪ Potential system performance disadvantages.

1.5.3.4 TOBACCO TRACEABILITY: OPTION 4

A solution that combines the traceability solution with security features by adding a unique identifier to the security feature.

KEY PRINCIPLES

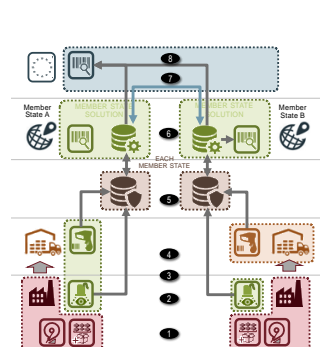
- Synergies between the traceability solution and security feature can be realised. Further synergies and cost savings for those Member States that have Tax Stamps / Fiscal markings that will fulfil the requirements of the security feature in TPD Article 16, and therefore will enable these to be used for this purpose.
- A tobacco control traceability solution which requires that some critical elements be controlled by the Member States, whilst less critical functions can be delegated to an independent provider OR other players:
 - Member States retain key responsibilities considered critical for a tobacco control regime and establish solution components and standards for recording the unique identifier of the secure label applied during manufacture. This equipment is installed in manufacturing premises but operated and serviced by a provider independent of the tobacco industry.

A data exchange mechanism is specified for manufacturers to provide additional data at time of manufacture (e.g. intended shipment route).

- Solution components that are considered lower risk such as recording distribution chain events from manufacture to last point prior to retail are operated by industry and data is submitted to the independent data storage provider using prescribed industry data exchange standards.
- EU Commission dictates the minimum data to be recorded and provides a means for EU agencies and other Member States to access this data under controlled circumstances to support risk management enforcement and investigation activities within the EU community.
- An independent data storage provider(s) appointed by the Commission and/or each Member State stores traceability data (recorded at the time of manufacture or import, and received from the distribution chain operators).

EU operates a query messaging service for the routing of tracing queries that span multiple Member State data repositories.

ANALYSIS



Option 4

Advantages	<ul style="list-style-type: none"> ▪ Retains independent oversight ▪ Reduced equip. requirements. ▪ Lower risk of prod. downtime. ▪ Control of SF stock ▪ Flexibility for manufacturers how to apply SF
Disadvantages	<ul style="list-style-type: none"> ▪ SF location potentially creates aggregation complexity ▪ Traceability queries require online connectivity ▪ Additional solution need for marking export products <p style="text-align: center;">Solution by Member State</p> <ul style="list-style-type: none"> ▪ Higher implementation and change management effort ▪ Integration of Member State level data sources required for EU-level oversight and tools for EU Agencies. ▪ Potential system performance disadvantages.

It should be noted that the four options have been developed for analysis and feasibility assessment purposes within the context of this report. Any future solution that may combine or contain variations of these should be assessed in terms of its compatibility with both the FCTC protocol and TPD for compliance and regulatory intent with respect to those agreements.

1.5.4 FOUR OPTIONS FOR SECURITY FEATURES

The survey of available security feature technologies indicated a diverse range of security features that can be combined to provide a competent security package with overt, semi-covert, covert and forensic elements. While there are therefore hundreds of combinations and permutations, the project Team considered four distinct scenarios in proposing the security feature packages options for further evaluation:

1. **A competent security feature package** using similar authentication technologies for consumers and law enforcement officials as used on a modern tax stamp.
2. A Security Feature package would be required **to supplement a “digital only” solution** (where the unique identifier and associated traceability data

are the only means to verify a product). This security feature package would therefore need to provide a basic set of authentication features (Overt and Forensic) to create some stronger measures for the potential detection of the illicit reproduction of unique identifiers from legitimate tobacco products onto illicit products.

3. A security package that includes an **emerging security feature** for material fingerprinting; and
4. A combined security feature package that considers **synergy benefits with the traceability solution** (required to complement Traceability Solution Option 4 in 8.5 below).

Option 1 – Similar to Tax Stamp	
Level 1 (Overt)	Optically Variable Device (Option 1A) or Optically Variable Ink (Option 1B) Overt Guilloche Pattern
Level 2 (Semi-Covert)	Micro text UV inks with bi-fluorescence reaction Covert Holographic Feature (1A) or Semi-covert Ink Effect (1B)
Level 3 (Covert)	Laser or Machine Readable Taggant
Level 4 (Forensic)	Forensic Marker
Tamper-proof	Frangible Paper and adhesive Die cuts (Kiss cuts) for self-adhesive labels
Paper	Frangible paper, tax stamp quality suitable for use in high speed label applicators (dry labels)
Application Method	Dry Label and Self Adhesive label Available as stacks or reels to suit manufacturers preferences

Option 3 – Addition of Material Fingerprinting	
Level 1 (Overt)	Optically Variable Device or Optically Variable Ink
Level 2 (Semi-Covert)	Fingerprinting Technology
Level 3 (Covert)	Fingerprinting Technology
Level 4 (Forensic)	Forensic Marker
Tamper-proof	Frangible Paper and adhesive Die cuts (Kiss cuts) for self-adhesive labels
Paper	Frangible paper, tax stamp quality suitable for use in high speed label applicators (dry labels)
Application Method	Dry Label and Self Adhesive label Available as stacks or reels to suit manufacturers preferences

Option 2 – Reduced Covert (semi-covert)	
Level 1 (Overt)	Optically Variable Device or Optically Variable Ink (Optional) Iridescent ink or foil
Level 2 (Semi-Covert)	Rely on Track and Trace Serialisation (separate from security feature) (Optional) Micro-particles
Level 3 (Covert)	Laser or Machine Readable Taggant
Level 4 (Forensic)	Forensic Marker
Tamper-proof	Frangible Paper and adhesive Die cuts (Kiss cuts) for self-adhesive labels
Paper	Frangible paper, tax stamp quality suitable for use in high speed label applicators (dry labels)
Application Method	Dry Label and Self Adhesive label Available as stacks or reels to suit manufacturers preferences

Option 4 – Includes Unique Machine Readable Code	
Level 1 (Overt)	Optically Variable Device or Optically Variable Ink Overt Guilloche Pattern
Level 2 (Semi-Covert)	Micro text UV inks with bi-fluorescence reaction Covert Holographic Feature or Semi-covert Ink Effect
Level 3 (Covert)	Laser or Machine Readable Taggant
Level 4 (Forensic)	Forensic Marker
Tamper-proof	Frangible Paper and adhesive Die cuts (Kiss cuts) for self-adhesive labels
Paper	Frangible paper, tax stamp quality suitable for use in high speed label applicators (dry labels)
Application Method	Dry Label and Self Adhesive label Available as stacks or reels to suit manufacturers preferences
Variable Data	Inclusion of unique identifier

To provide a baseline for comparison, four different security feature options were prepared and shared with a subset of security feature providers (a sample of respondents of the previous survey conducted as part the primary technology solution providers survey). Further, the four options included some minor variations in specific security feature elements (either for overt, covert or forensic) to facilitate the discussion with security feature providers on package design considerations, potential compatibility considerations and cost implications. The analysis, feedback indicated that:

- There are a considerable number of overt, covert and forensic security elements that can be combined to create a competent security feature as contemplated in Article 16.
- There are numerous covert security feature options that can be considered suitable for the invisible component of the security feature. In contrast, there are limited options for effective overt (visible) security element that enables authentication of the security feature using sight / touch, and without a device.
- For several security elements, choice of providers is very limited, in an industry where secrecy and trust is important, there appears to be a practice of well-established relationships between “trusted” providers. This was found to be the

case for several security components, including security inks, security foils and security paper. Similarly in the case of emerging technologies such as fingerprinting, there are again limited solution providers.

In evaluating the security feature packages, several additional considerations for the EU Commission are presented in the report that include:

- Establishing controls around the production of the security feature, input materials, finished product and accounting for usage by Tobacco Manufacturers
- Review of security feature every 3 to 5 years, (minimum every 5 years) to evaluate the security feature elements;
- It is envisaged that consolidating production of security features for the collective EU market is unlikely to yield any significant cost advantage over larger Member States sourcing individually. For those EU Member States with lower volume requirements, there may be an incentive to pool security feature sourcing to reduce cost implications
- Consideration of size, flexibility of application method and location be allowed to accommodate the varieties of packaging types, and the mix of production processes associated with tobacco products in the EU that spans very high volume automated cigarette pack manufacture through to specialty low volume and hand packaged tobacco items.
- The option to use the security element as a supporting component of the traceability solution was also considered (providing a control mechanism for Traceability Option 1, 2 and 3). Where the security feature provides a function for volume verification, this can be used as a reconciliation element to validate the tobacco traceability solution.

1.5.5 ANALYSIS OF DATA STORAGE OPTIONS

The data storage requirements were reviewed in relation to each of the four traceability options in the EU. The following issues were taken into consideration:

- Data storage requirements
- Compliance costs to traceability solution practicality of implementation with multiple solution providers
- Implications and requirements related to the data storage contracts with an independent third party
- Estimate data size of a tobacco traceability solution operating across the EU.

Further, recommended contract elements for consideration by the EU and Member State authorities were summarised (including audit and service requirements and proposed terms of reference).

Based on the outcome of the analysis, the data storage requirements proved less complex and voluminous than originally anticipated, implying that the contractual requirements and process would be within the ambit of a single data management service provider operating in the EU.

- Data size is not an impediment to the selection of a sole source supplier of data storage (e.g., estimated data for one year = +/-three terabytes).
- Compliance for Manufactures, EU Member States and suppliers would be significantly simplified if storage and processing of data occurred at a single site.
- The use of a single repository for storage of traceability data and processing would ensure compatibility of data sets, reduce the complexity of information assembly and help ensure overall data quality and integrity.

- Selection of a single data storage and processing provider would appear to be the easiest to implement, while also being the easiest to administer and the most cost effective (e.g., the cost of conducting 26 separate tenders alone, for Member State level storage would far exceed the cost of data storage with a single provider).

1.6 COST BENEFIT ANALYSIS

The Cost Benefit Analysis supplements the overall assessment with an empirical perspective related to the costs, benefits and feasibility of the proposed solutions. It outlines the potential impact of such solutions on tobacco manufacturers, entities that operate in the tobacco distribution chain and EU Member States.

The cost / benefit analysis is a modelling exercise to estimate what the costs would be using limited inputs, whilst benefits are modelled using techniques used in previous reports (e.g. EU Commission, WHO and various industry reports). There is an inherent challenge measuring benefits related to illicit trade – by its very nature it attempts to be “invisible”, and estimates of its magnitude need to be treated with caution where they may be ulterior motives by certain actors to overstate or understate.

In addition, while we have attempted to estimate the costs using information that has been shared during the study, it must be noted that both tobacco manufacturers and solution providers are competitors and understandably not willing to reveal cost information related to solutions outside of a commercial initiative (e.g., competitive tender or contract). It is not the intention of this report to establish these actual commercial amounts, but rather the indicative amounts in order to facilitate the analysis.

As referred to in this Report, the main sources of information consist of a series of publicly available reports and studies relative to the subject matter; as well as responses to the several surveys that were prepared and distributed to relevant stakeholders (Member States, traceability and security feature solution providers, industry associations/professional bodies and the tobacco manufacturers themselves). It was not possible to obtain specific numbers in many instances and this required assumptions to be made in the analysis where cost data was not available from survey responses or via the public domain¹⁶. As these have an impact on the end-result of the cost/benefit analysis, the assumptions have been clearly outlined.

With the exception of benefits, where alternative scenarios were considered for the illicit trade figures, no sensitivity analysis was carried out for the assumptions used throughout this report.

1.6.1 SUMMARY OF FINDINGS

The four solution options for both traceability and security features are proposed in a manner to meet most aspects of the identified problem statement. While the costs associated with these different options may differ, benefits are related to the solution objectives that are similar across all the options. As there is no effective way to differentiate the quantitative benefits for these individually, this study analysed their impact from a holistic point of view, assuming that any option selected would achieve similar objectives, and to some degree reduce the number of illicit tobacco products on the EU market. All other benefits considered were estimated as a result of this reduction.

¹⁶ Some market data for various hardware and software components was obtained via the public domain directly from relevant suppliers.

Despite the fact there is no effective way to differentiate impacts in benefits from one option to another, key success factors and advantages / disadvantages of each of them can influence the likelihood of realizing those benefits in variable extent, so one should avoid to conclude that the solution to be chosen will simply be the cheapest one (a lesser degree of benefits realization could negatively compensate apparent savings in costs).

The cost analysis was done separately for each of the four traceability solutions and security features options, taking into consideration three key stakeholders: Member State authorities, tobacco manufacturers and distribution chain operators (including wholesalers and other agents / distributors comprised of Vending Machines Service Organisations and Mobile Sales Force Organisations).

It is important to highlight that there are different starting points related to the stakeholders considered within the cost model scope. As a result of the tobacco industry anti-smuggling agreements signed between certain manufacturers and the EU and certain Member States, several large tobacco manufacturers have already started implementing traceability solutions within their respective supply chains. The tobacco industry's solution has been used as the basis for each of these and has commenced limited implementation at Philip Morris, Japan Tobacco International, Imperial Tobacco and British American Tobacco.

Indications from information shared during stakeholders engagement are that industry's solution has been fully implemented (pack level tracking) on approximately 5% of the total production lines within the EU and implementation is on-going with each of the four largest manufacturers, albeit at a varied pace. The cost benefit analysis has taken these survey responses into consideration, however, since each of the organisations have undertaken the initiative on their own, with their own chosen systems integration vendors and technology choices, (e.g. ERP software integration, cameras, printers, etc.) a customized approach had to be developed. This is the only way to ensure an "apples-to-apples" analysis that is based on a common set of assumptions and data inputs, so the degree of implementation of each participant of the survey was not considered.

The costing analysis for wholesalers and distributors was calculated as a whole, as the impact on the distribution channel is expected to be similar across the four options.

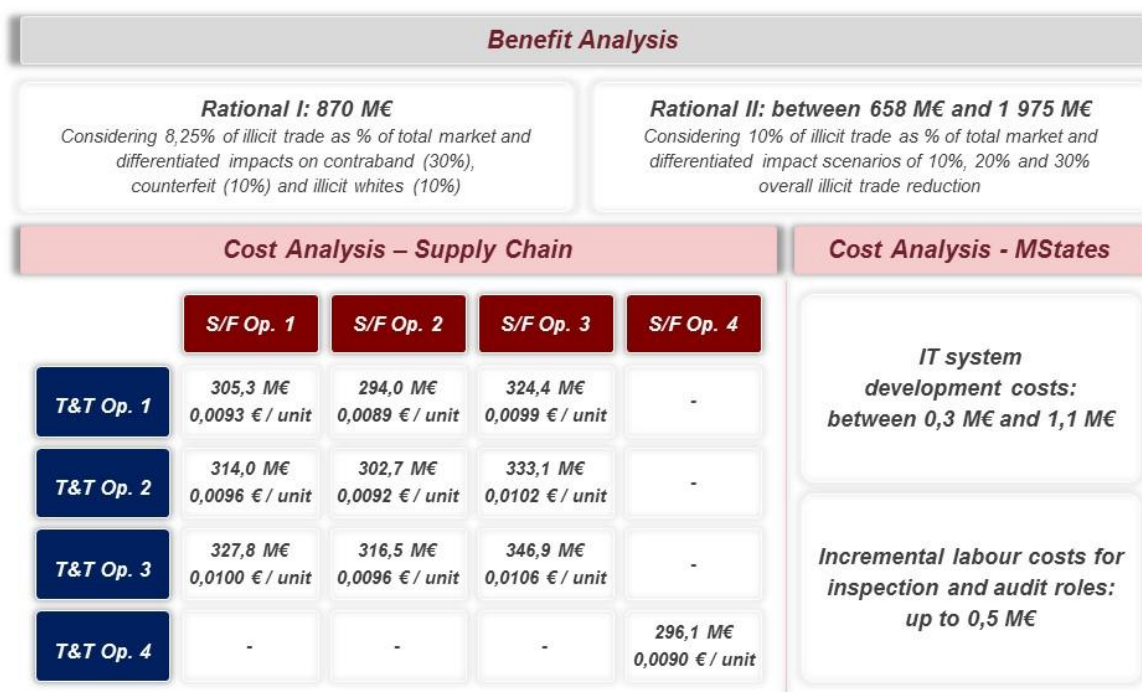
The TPD outlines the tobacco traceability requirements (Article 15) and security feature requirements (Article 16). Therefore, to identify the overall costs, the model requires that you consider the combination of the traceability cost component, together with a security feature solution, taking into account the interdependency between the fourth option of both.

In addition to the cost impact on manufacturers and distributors, it is important to understand the economic implications of the four proposed traceability solution options on Member States. This assessment was performed as a separate exercise and considered costs associated with the development and maintenance of an IT system to run the agreed traceability solution and labour costs related to additional personnel to support MS authorities' monitoring, controlling and enforcement activities.

Such costs were calculated as if a system was developed for a single Member State, rationale that we have followed for a set of reasons: one, the fact that requirements of such system are not known, the same applying to EU country specific status – we have then calculated costs for an application that complies to the TPD's requirements, regardless of what currently exists in the countries; two, the fact that introducing a multiple factor of 28 for 28 Member States in the calculations would not be reasonable, given that rates for system integrators significantly vary from country to country. Even so, for this last item in particular the project team has used two different daily rates for valuing the development effort, in order to recognize that investments will vary within the EU, thus allowing for a cost range to be determined.

Finally, despite having used a conservative approach particularly for the cost estimation component, the project team suggests that a competitive bidding process, both for hardware and software development/acquisition, will probably allow significant savings to be realised.

Total annualized benefits and cost (OPEX + depreciation) impacts for the whole EU are shown below:



In conclusion, different approaches and combinations can be used, considering the different individual options. The cost/benefit analysis shows that no matter which traceability and security feature option is selected, the benefits clearly outweigh the costs from both economic and social perspectives.

1.7 CONCLUSIONS AND RECOMMENDATIONS

This final report is a thorough and extensive document with a high degree of detail encompassing the main components of a future track and trace solution for the EU. The report was not intended to provide tender ready specifications for the Commission to immediately go out to the market for a traceability solution, but rather to inform the future evolution of the EU’s tobacco traceability strategy and related activities.

The four options outlined in this report provide a vehicle to distil out multiple options, decision points and performance criteria for future consideration and action. Additional analysis and decisions will be required in a number of areas in order for the Commission to be in a position to commence with the implementation of a solution. This would include, *inter alia*, agreement on a governance model for the system (e.g., Member State or Commission level), development of system user requirements, vulnerability assessment of solution options, final system architecture and security feature package.

The following table summarises some of the key issues that will require further consideration (in some cases analysis) and decisions to be made.

TRACEABILITY

#	Issues for Consideration	Discussion and Recommendations
1	Location and placement of the unique identifier	<ul style="list-style-type: none"> Diversity of configurations of tobacco manufacturing lines, product and packaging types. It is recommended that EU standards allow flexibility in the choice of location for the unique identifier on the tobacco product.
2	Data forming part of the Unique Identifier	<ul style="list-style-type: none"> Technical constraints and current business processes (what is known at time of manufacture) may impact information that forms part of the unique identifier It is therefore recommended that additional flexibility be provided for some of the required data elements to be recorded in the data repository and linked to the unique identifier
3	Security of Unique Identifiers	<ul style="list-style-type: none"> Ensuring unique identifiers are not predictable with safeguards against generation by unauthorised parties. Encryption of the unique identifier may provide an additional security advantage in the context of a traceability system, and asymmetric encryption provides a mechanism to segregate keys used for encryption and keys used for decryption.
4	Interoperability of traceability solutions and standards across Member States	<ul style="list-style-type: none"> Preventing different EU traceability requirements applied to a single production line Recommended to prevent possible duplication of equipment and solutions on a tobacco production lines.
5	Readiness of distribution chain operators	<ul style="list-style-type: none"> It is recommended a readiness survey be conducted of the distribution chain operators to guide the implementation model. A segmented and differentiated implementation approach may be considered for different categories of distribution chain operators (e.g. vending machine operators, cash & carry wholesalers and mobile sales forces).
6	Optimising operational impact vs. granularity of supply chain events recorded	<ul style="list-style-type: none"> It is recommended that the solution requires all dispatch and receipt operations by distribution chain operators to be recorded (in-out).
7	Submission of commercial documents supporting traceability events	<ul style="list-style-type: none"> Article 15 §2(k) of the TPD identifies the requirement for commercial documents and related business event data that will need to be referenced or recorded by the traceability solution. The report identifies three options in which this potentially could be implemented with progressively demanding implications and benefits for different stakeholders. It is recommended that information requirements for these records and data are developed by the Member States and EU Commission, and that if necessary (based on the impact on manufacturers and distribution chain operators), a phased implementation approach be adopted.

#	Issues for Consideration	Discussion and Recommendations
8	Potential integration with Customs and Excise Systems	<ul style="list-style-type: none"> ▪ Customs: Linkage between the traceability solution and Member State export systems to record the exit of tobacco products from the EU territory, assist volume reconciliation, support customs risk analysis and provide basis to detect potential diversion of exported goods re-entering the EU market. ▪ Traceability solution and security feature could assist Customs officials at frontier validate legitimate tobacco consignments and provide data to support risk management activities. ▪ Excise: It is recommended that the Commission conducts a further assessment of a potential linkage between the EU EMCS solution and proposed tobacco traceability solution to strengthen controls related to tobacco movements under duty suspension. Potential data synergies should be further assessed in terms of using traceability data as a reconciliation against excise declarations, as well as revenue forecasting and planning.
9	EU and Member State market surveillance / field inspection activities	<ul style="list-style-type: none"> ▪ Different degrees of sophistication can be considered in providing an application to support EU and MS authorities in the context of a tobacco traceability solution.

SECURITY FEATURES

	Issues for Consideration	Discussion and Recommendations
1	Ensuring adequate control of the security feature before, during and after its production	<ul style="list-style-type: none"> ▪ A control system should be in place in accordance with security printing standards (such as ISO14298:2013(E) Management of Security Printing Processes, NASPO certification), to ensure produced security features, input materials and waste elements materials are controlled. ▪ It is recommended that the security feature itself is manufactured with at least some basic serialisation of the security feature itself (even such as basic batch numbers). This provides the basis for controls and accountability for possession of the security feature elements. (Note option 4 includes the unique identifier on the security feature which would provide such controls by default).
2	Risk of counterfeiting of the security feature	<ul style="list-style-type: none"> ▪ It is recommended that the security feature package be reviewed every 3 to 5 years, (minimum every 5 years) to evaluate the security elements used to create the security features.
3	Economies of scale/volume discounts	<ul style="list-style-type: none"> ▪ For those EU Member States with small tobacco markets and associated low volumes of security feature requirements there will be an economies of scale advantage to pool security feature sourcing ▪ However, with the current structure of current security printers, it is envisaged that an economies of scale ceiling would be reached by consolidating production of security features for the collective EU market.

	Issues for Consideration	Discussion and Recommendations
4	Flexibility to accommodate the variety of tobacco packaging	<ul style="list-style-type: none"> ▪ Flexibility for the label application method is allowed to accommodate the varieties of packaging types, and the mix of production processes associated with tobacco products.
5	Security feature size	<ul style="list-style-type: none"> ▪ It is recommended that a mix of security feature sizes be specified for different categories of tobacco products. Where stamps / labels are used for high speed cigarette manufacturing lines, compatibility with existing label applicators size requirements is anticipated to provide both a reliability and cost advantage.
6	Security feature position on the tobacco product	<p>The following considerations relate to the placement of the security feature on the tobacco product units:</p> <ul style="list-style-type: none"> ▪ As indicated in Article 16, the security feature should be irremovable, and therefore applied directly to the tobacco pack, and under any clear wrap materials ▪ Placement under the clear wrap also provides a level of protection to the security feature during transport; ▪ It is recommended that the security feature is placed in such a manner over the tobacco pack opening (for both soft packs and flip-top style packs) ▪ Placing the security feature near the top of the pack where it will not be obscured by retail stands also allows quick visual inspection that displayed stock is compliant.

2 DEVELOPING THE PROBLEM STATEMENT

2.1 BACKGROUND AND CONTEXT

2.1.1 THE SIZE OF ILLICIT TOBACCO TRADE

Measuring illicit trade of cigarettes is methodologically challenging for varying reasons. First, it is an illegal activity and illegal traders are unlikely to record their activities. Also, for security reasons, data on illicit trade is usually difficult to obtain, as law enforcement agencies often prefer not to publicise the scope of their activity. Furthermore, all methods to estimate illicit trade have their limitations and not all studies clearly describe their methodology or these limitations.

Transparent, public data on illicit tobacco trade is missing in most European countries. KPMG, a major consultancy and professional services firm, conducted research on illicit trade as a part of the agreement between the EU and Philip Morris International (PMI). According to KPMG, contraband trade accounted for 9.9% of total consumption in 2010 and 11.1% in 2012.¹⁷ Critique of the KPMG estimates includes, among others that the methodology for the collection of the empty packs in the report is insufficiently explained to judge its validity and that the report relies heavily on expertise and data provided by the tobacco industry.¹⁸ It has been recently reported that *looking at Member States' seizure data of 2013, it turns out that eight of the ten most prominent cigarette brands in seizures were cheap whites*. However, these statistics seem to rely on a broad definition of cheap whites, which includes all but brands of the four manufacturers with which the EU and the Member States have Co-operation agreements^{19,20}.

2.1.2 THE CHANGING NATURE OF ILLICIT TRADE

In the 1990s and in the beginning of this millennium, the main type of illicit trade was large-scale cigarette smuggling: containers of cigarettes were exported, legally but duty unpaid, to countries where these products had no market and where the cigarettes disappeared into the contraband market.²¹

During the period 1996-2012, cigarette seizures in the European Union were highest in 1999-2000 (around 6 billion a year), when certain tobacco companies were accused of being involved in the smuggling operations.

Table 5. Cigarette seizure data in the EU-15 (1996-2003), EU-25 (2004-2006) and EU-27 (2007-2012).

¹⁷ KPMG. Project Star 2012 Results [Internet]. 2013;

¹⁸ Gilmore AB, Rowell A, Gallus S et al, Towards a greater understanding of the illicit tobacco trade in Europe: a review of the PMI funded "Project Star" report. *Tob Control*. 2013 Dec 11;

¹⁹ Speech of former Commissioner A. Semeta as delivered in the European Parliament on 7 October 2014.

²⁰ EU Commission's Communication Stepping up the fight against cigarette smuggling and other forms of illicit trade in tobacco products – A comprehensive EU Strategy.

²¹ Jha P, Chaloupka F J, Curbing the epidemic. Governments and the economics of tobacco control, World Bank, Washington DC, 1999.

EU-15		EU-25		EU-27	
Year	Billion cigarettes	Year	Billion cigarettes	Year	Billion cigarettes
1996	3.1	2004	4.1	2007	4.8
1997	2.6	2005	4.4	2008	4.6
1998	4.7	2006	4.6	2009	4.7
1999	5.7			2010	4.7
2000	6.2			2011	4.4
2001	4.8			2012	3.8
2002	3.6				
2003	3.3				

Source: European Anti-Fraud Office (European Commission)

It should be noted that large seizure data have their limitations and provide only an indication of trends in the illicit market. Seizures are a function of law enforcement activity and may vary according their efficiency and intensity. In addition, they don't take into account the illicit trade of smaller consignments (below 100.000 cigarettes).

In Europe, while large-scale smuggling of well-known brands decreased, other types of illicit trade, such as counterfeiting, emerged. In the United Kingdom (UK), for instance, 46% of all large cigarette seizures in 2007-8 were counterfeit. The bulk of counterfeit cigarettes are manufactured in China and, to a lesser extent, Eastern Europe.²² China continues to be the source country for counterfeit cigarettes in the EU, according to a recent EU report.²³ Illicit consignments seized were shipped either directly to European seaports or transhipped via Singapore and Malaysia, where the illicit trade is aggravated by the insufficient control in the free zones.

Illegal factories also exist in EU Member States and are a significant source of counterfeit cigarettes.²⁴ The number of known illegal factories in the EU has increased rapidly from five in 2010 to nine illegal factories in 2011, and also more recently an important number of illegal factories have been closed down.²⁵

Besides illegal manufacturing, another change in the illicit trade was the emergence of the so-called 'cheap whites', the development of new cigarette brands, produced in an open manner at well-known locations, which are mainly intended for the illegal market in another country. 'Cheap whites' or cigarettes are produced (often legitimately) in their country of origin at a very low cost and are destined to be illicitly sold in other jurisdictions and do not respect the legal requirements in the jurisdiction of destination. Among the best known 'cheap whites' in Europe are 'Fest' and 'Jin Ling', a cigarette brand with a Chinese name, manufactured in Russia, apparently in accordance with Russian domestic law, with the look and the taste of an American blend (Camel), but destined for the illegal market in the EU. Other 'cheap whites' are produced in particular in the UAE, Belarus, China and other Asian countries, as well as in certain Member States.^{26 27}

²² HM Revenue & Customs, Tackling Tobacco Smuggling Together, London, November 2008.

²³ European Commission. Stepping up the fight against cigarette smuggling and other forms of illicit trade in tobacco products – A Comprehensive EU Strategy. Brussels; 2013 Jun.

²⁴ Europol, EU organised crime threat assessment, OCTA 2010, The Hague, 2011.

²⁵ European Commission. Stepping up the fight against cigarette smuggling and other forms of illicit trade in tobacco products – A Comprehensive EU Strategy. Brussels; 2013 Jun.

²⁶ KPMG, Project Star results 2011, 2012. Page 52

Despite the focus in the media on counterfeits and 'cheap whites', the illicit trade of legally branded cigarettes remains at high levels in Europe, in particular due to big tax and price differentials vis-à-vis non-member countries. The modus operandi of the smuggling operations for those legally branded cigarettes can compromise both large consignments of smuggled cigarettes, as well as "ant smuggling". Ant smuggling refers to the organized and frequent crossing of borders by a large number of individuals with relatively small amounts of low-taxed or untaxed tobacco products. The main countries of origin for illicit cigarettes from the Eastern border in the European Union are Russia, Ukraine and, increasingly, Belarus, from where many products seized are genuine. This means that they are produced legally, but in quantities greatly exceeding local demand in source countries.²⁸ These "extra" cigarettes disappeared in Ukraine but also Moldova and other false destinations and fuelled the black market in the rest of Europe.²⁹ Customs officials in the Baltic countries and Poland have recently noticed that more illicit cigarettes are originating from Belarus.³⁰ A recent study indicates that a probable cause of the sales increase is smuggling of large amounts of Belarus-produced cigarettes to other countries.³¹

2.1.3 THE AGREEMENTS WITH FOUR MAJOR TOBACCO COMPANIES

In July 2004, the EU and 10 Member States concluded enforceable and legally binding anti-smuggling agreements with PMI, which agreed to pay the EC \$1 billion over 12 years. Similar agreements were concluded with JTI in December 2007 (agreed payments: \$400 million), with British American Tobacco (BAT) in July 2010 (agreed payments: \$200 million) and with Imperial Tobacco Limited (ITL) in September 2010 (agreed payments: \$300 million).

The agreements require the four companies to control future smuggling through a range of measures, which included controlling the distribution system and contractors supplied, and implementing tracking and tracing measures. Although the first Agreement originally covered only 10 Member States, currently the EU Commission and 27 Member States have signed the four Agreements, and one Member State has signed two of the agreements.

2.1.4 THE EU POLICY TO COMBAT ILLICIT TRADE OF TOBACCO PRODUCTS

On 6th June 2013, the Commission published its communication to step up the fight against illicit trade in tobacco products. The communication sets out the Commission's proposals for a comprehensive EU strategy to tackle this illicit trade. The communication is accompanied by an action plan, which contains 50 measures, and time lines and outcome measures to be developed and implemented over the next two years.³² The objective is to protect the financial interests of the EU and its Member States. Cigarette

²⁷ World Customs Organization, The illicit trade Report 2012, Brussels 2013.

²⁸ European Commission. Stepping up the fight against cigarette smuggling and other forms of illicit trade in tobacco products – A Comprehensive EU Strategy. Brussels; 2013 Jun.

²⁹ Lavrov V. Ukraine's 'lost' cigarettes flood Europe. Washington, The Center for Public Integrity, 2009. <http://www.publicintegrity.org/investigations/tobacco/articles/entry/1438/>

³⁰ Czyzowicz W. The nature of illicit trade in Tobacco and Alcohol products on the Eastern border, Customs book Library. Warsaw; 2013.

³¹ Krasovsky, K, Dynamics of smoking prevalence and tobacco products market in Belarus. Tobacco control and public Health in Eastern Europe, 2012: 5(1), 9-16.

³² European Commission. Stepping up the fight against cigarette smuggling and other forms of illicit trade in tobacco products – A Comprehensive EU Strategy. Brussels; 2013 Jun.

smuggling causes yearly losses to Member States and the EU of at least € 10 billion in evaded customs duties and taxes.

The communication notes that the seizure of "other brands" is steadily increasing. "Other brands" are defined as brands not produced by the four manufacturers with which the EU has cooperation agreements.

The communication lists a range of approaches to be implemented by the EU institutions (Commission, Council, Parliament and the Member States). The action plan provides timelines (between 2013 and 2015) and outcome indicators, without the description of specific objectives to achieve.

The strategy proposes specific actions in 4 key areas:

- Measures to decrease incentives for smuggling activities
- Measures to improve the security of the supply chain
- Stronger enforcement of tax, customs, police and border authorities
- Heavier sanctions for smuggling activities

The description of the planned measures is general. The planned measures include:

- More investment in equipment and IT tools to protect borders
- Improved intelligence gathering, risk management and Joint Customs Operations
- Enhanced cooperation among EU agencies and with major source and transit countries
- Strengthened sanctions
- Sharing of expertise and best practises
- Endorsement of the WHO Framework Convention on Tobacco Control (FCTC) Protocol to eliminate illicit trade in tobacco products (the 'Protocol')
- The adoption of the Tobacco Products Directive

2.1.5 A GLOBAL RESPONSE: THE FCTC AND TRACK AND TRACE SYSTEMS

The global scope and multifaceted nature of the illicit tobacco trade requires a coordinated international response and improved global regulation of the legal tobacco trade. The illicit tobacco trade is regulated by article 15 of the World Health Organization (WHO) FCTC and by the Protocol, which has been negotiated as a supplementary treaty to the World Health Organisation's (WHO) Framework Convention on Tobacco Control. The Protocol, adopted at the fifth conference of the parties in November 2012, will come into force on the 90th day following the date of the 40th ratification of the protocol. Only parties, which ratify the protocol, will be bound by its obligations.

As at the end 2014, 54 Parties to the WHO FCTC (including 20 States from the WHO European Region³³) have signed, and six States (Austria, Gabon, Mongolia, Nicaragua, Spain, Uruguay) have ratified the Protocol. Enforceable measures to control the supply chain and international cooperative measures, including information sharing and cooperation in the investigation and prosecution of offences, are at the heart of the Protocol to Eliminate Illicit Trade in Tobacco Products.

³³ For the list of WHO European Country regions see <http://www.euro.who.int/en/countries>

The 'Protocol' key requirements

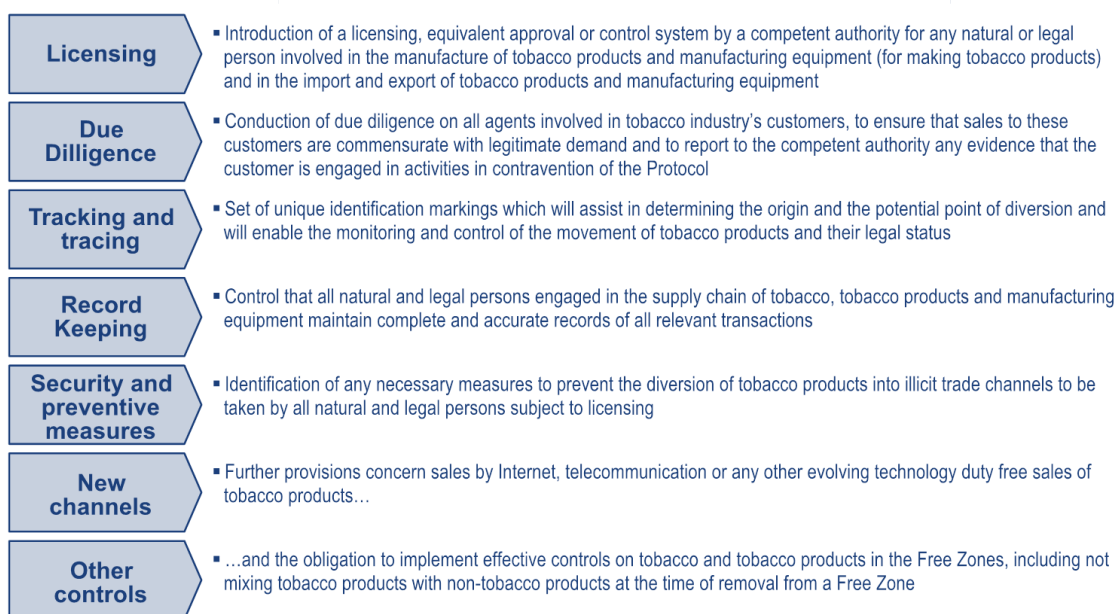


Figure 12 – The Protocol to Eliminate Illicit Trade in Tobacco Products was adopted by the Conference of the Parties to the WHO Framework Convention on Tobacco Control (FCTC)

One of the core measures of the protocol is the tracking and tracing regime (article 8). According to this Article, each Party shall require that unique, secure and non-removable identification markings, such as codes or stamps, are affixed to or form part of all unit packets, packages and any outside packaging of cigarettes within a period of five years, and other tobacco products within a period of ten years of entry into force of the Protocol.

The aim of the tracing system is to secure the supply chain of cigarettes produced legally and to thereby assist in the investigation of illicit trade of tobacco products, which should be a priority in the WHO European Region. Compared to other WHO regions, the WHO European Region has the highest smoking prevalence, the highest proportion of deaths attributed to tobacco, the highest cigarette tax levels and the highest number of seized cigarettes in the world [please add a footnote with the source of this information]. For these reasons, Europe is at the highest risk of the tobacco control system being undermined with illicit trade and therefore it is the region to benefit the most from any potential reductions in the volume of illicit trade.

2.1.6 AN EU RESPONSE: THE TPD AND TRACK AND TRACE SYSTEMS

An EU tracking and tracing system of tobacco products and for security features is foreseen in Article 15 and 16 of the Tobacco Products Directive 2014/40/EU of 3 April 2014.

The rationale for the tracking and tracing system in the Tobacco Products Directive 2014/40/EU is that considerable volumes of illicit products, which do not comply with the requirements laid down in Directive 2001/37/EC, enter the market and that such products undermine the free circulation of compliant products and the protection provided for by tobacco control legislation, explained in the recitals 29-31 of the Directive:

- (29) Considerable volumes of illicit products, which do not fulfil the requirements laid down in Directive 2001/37/EC, are placed on the market and there are indications that these volumes might increase. Such illicit products undermine the free circulation of compliant products and the protection provided for by tobacco control legislation. In addition, the FCTC requires the Union to combat illicit tobacco products, including those illegally imported into the Union, as part of a comprehensive Union policy on tobacco control. Provision should, therefore, be made for unit packets of tobacco products to be marked with a unique identifier and security features and for their movements to be recorded so that such products can be tracked and traced throughout the Union and their compliance with this Directive can be monitored and better enforced. In addition, provision should be made for the introduction of security features that will facilitate the verification of whether or not tobacco products are authentic.
- (30) An interoperable tracking and tracing system and security features should be developed at Union level. For an initial period only cigarettes and roll-your-own tobacco should be subjected to the tracking and tracing system and the security features. This would allow **manufacturers** of other tobacco products to benefit from the experience gained prior to the tracking and tracing system and security features becoming applicable to those other products.
- (31) In order to ensure independence and transparency of the tracking and tracing system, manufacturers of tobacco products should conclude data storage contracts with independent third parties. The Commission should approve the suitability of those independent third parties and an independent external auditor should monitor their activities. The data related to the tracking and tracing system should be kept separate from other organisation related data and should be under the control of, and accessible at all times by, the competent authorities from Member States and the Commission.

2.1.7 THE AGENCIES WITH AN INTEREST IN THE EU TRACK AND TRACE SYSTEM

The main department within the European Commission services involved in the follow-up of Article 15 and 16 of the TPD is the Directorate General for Health and Consumers (DG SANCO) whose task it is to guarantee the free movements of compliant tobacco products and to ensure a high level of public health in the EU.

Other Directorates General might also benefit from a traceability and security marking system for tobacco products, including the Directorate General for **Taxation and the Customs Union**, specifically regarding tax and revenue considerations; for example, in the Excise Movement and Control System (EMCS), the VAT Information Exchange System (VIES) and the Automated Import and Export Systems. A traceability system for tobacco products might provide support for investigations into the eventual fraud with the ECMS system, VIES or the Automated Import and Export System.

- **EMCS** is the computerisation and mutual exchange of information concerning movements of excisable goods under duty suspension between the actors involved in these movements. EMCS is used to monitor bulk movements under excise duty suspension (at the truck, container, pallet level and so on), but does not cover:
 - (a) Monitoring at the packet or carton level
 - (b) Monitoring once the excise duty in the country of consumption has been paid ('release for consumption')

- (c) Monitoring of goods at import before release into free circulation (national import system responsibility)
- (d) Non-community goods in transit (NCTS)
- (e) Raw tobacco (non-excise good)
- **VIES** is an electronic means of transmitting information relating to VAT-registration (= validity of VAT-numbers) of companies registered in the EU. Furthermore, information relating to (tax exempt) intra-Community supplies between Member States' administrations is also transmitted via VIES.
- The objective of the **Automated Import System** is to ensure that import operations started in one Member State can be completed in another Member State without re-submission of the same information. This includes the exchange of electronic messages related to the different stages of the operations amongst the various actors (customs, traders and other governmental administrations).
- The objective of the **Automated Export System** is to ensure that export operations started in one Member State can be finalised in another Member State without re-submission of the same information.
- The **European Anti-Fraud Office (OLAF)** is the sole investigative body at EU level. It works in close cooperation with national law enforcement agencies and customs services both inside and outside the EU to prevent, detect, investigate and collect evidence – so that evaded tobacco products duties can be recovered and perpetrators prosecuted. Moreover, OLAF is the service in lead for the conception and implementation of the Tobacco Products Anti-Smuggling Action Plan.³⁴
- Other agencies, within an EU context, which would benefit from the tobacco products traceability system, are EUROPOL and Eurojust. **EUROPOL** supports law enforcement agencies in the EU in their struggle against the illegal manufacture and distribution of cigarettes and tobacco products.
- **Eurojust** stimulates and improves the coordination of investigations and prosecutions between the competent authorities in the Member States and improves the cooperation between the competent authorities of the Member States, in particular by facilitating the execution of international mutual legal assistance and the implementation of extradition requests.

International organizations involved in combating the illicit trade of tobacco products, such the World Customs Organization (WCO), INTERPOL, the United Nations Office on Drugs and Crime (UNODC), and the Secretariat of the WHO Framework Convention on Tobacco Control might also benefit from a EU traceability system for tobacco products, by collecting intelligence and facilitating investigations:

- The **WCO** has been working with other regional and international organizations in an attempt to identify the best possible enforcement strategies to counter the illicit trade in tobacco products, including joint Customs enforcement projects.
- **UNODC** provides Member States help to address the threat posed by drugs, crime and terrorism.
- The **INTERPOL** mission is "Preventing and fighting crime through enhanced cooperation and innovation on police and security matters".

³⁴ Communication from the Commission to the Council and the European Parliament, Stepping up efforts to fight against cigarette smuggling and other forms of illicit trade in tobacco products– A comprehensive EU Strategy, SWD (2013) 193 final.

- The **Secretariat of the WHO FCTC** task is to support Parties in fulfilling their obligations under the FCTC (Article 15 of the FCTC and the Protocol to eliminate illicit trade in tobacco products, which is open for ratification by the Parties).

Further, there are several organisations seeking greater co-ordination and cooperation between law enforcement organisations to combat illicit activities such as the Global Initiative Against Transnational Organized Crime.

In conclusion, DG SANCO is the first interested party regarding the implementation of the traceability and security marking system envisaged in Articles 15 and 16 of the Tobacco Products Directive 2014/40/EU, but any solution should reconcile the documental and physical flow of the tobacco products and consider integration and synergy with the work done in other DGs, such as the OLAF and DG Taxation and Customs Union, and by European and international organizations whose aim is to combat the illicit trade of tobacco products.

2.1.8 WHO FCTC RESPONSE

The World Health Organization Framework Convention on Tobacco Control (WHO FCTC) is the first treaty negotiated under the auspices of the World Health Organization. The WHO FCTC is an evidence-based treaty that reaffirms the right of all people to the highest standard of health. The WHO FCTC represents a paradigm shift in developing a regulatory strategy to address demand reduction, as well as supply reduction issues.

The demand reduction provisions in the WHO FCTC are contained in Articles 6-14. Article 11 (labelling) and Article 13 (advertising) are considered to be the key provisions of the FCTC, because they contain the strongest obligations such as the ban on tobacco advertising and the obligations to have health warnings. In terms of health warnings members must ensure that these occupy no less than 30% of the principal display area. However, the WHO FCTC encourages that these be more than the 30% minimum, and specifies that health warnings should be 50% or more of the principal display area.

The supply reduction provisions in the WHO FCTC are contained in Articles 15-17: Illicit trade in tobacco products, sales to and by minors and provision of support for economically viable alternative activities.

The Convention entered into force on 27 February 2005 - 90 days after it had been acceded to, ratified, accepted, or approved by 40 States. In total, 168 parties have signed and 177 parties have ratified the FCTC, which makes it one of the most widely embraced treaties in UN history.

2.1.9 ARTICLE 15 OF THE WHO FCTC

Tobacco smuggling has become a critical public health issue because it brings tobacco into markets cheaply, making cigarettes more affordable and thus stimulating consumption, consequently increasing the burden of ill health caused by its use. It also affects other provisions concerning tobacco control such as the effort to eliminate the undesired additives³⁵.

In the World Bank report (1999), *Curbing the Epidemic*, it was observed that measures to control the supply of tobacco are less promising. However, one supply-side measure is key to an effective strategy for tobacco control: action against smuggling. According to the World Bank, "effective measures included prominent tax stamps and local-language

³⁵ Jess Alderman, Tobacco Control Legal Consortium, Strategies to Combat Illicit Tobacco Trade, Tobacco Control Legal Consortium, Saint Paul, Minnesota, 2012.

warnings on cigarette packs, as well as aggressive enforcement and consistent application of tough penalties to deter smugglers.”

In the preamble of the FCTC it was recognized that “cooperative action is necessary to eliminate all forms of illicit trade in cigarettes and other tobacco products, including smuggling, illicit manufacturing and counterfeiting. ”

Article 15 of the FCTC deals with the illicit trade in tobacco products and stipulates in its first paragraph that “the elimination of all forms of illicit trade in tobacco products (..) are essential components of tobacco control.”

Article 15 was the first agreed Article during the FCTC negotiations, already in October 2002. It contained some general obligations in relation to markings, tracking and tracing, penalties, monitoring and can be considered as a compromise text between three parties which were the most interested in this issue (USA, EU and Canada).

According to Article 15, § 2: “Each Party shall adopt and implement effective legislative, executive, administrative or other measures to ensure that all unit packets and packages of tobacco products and any outside packaging of such products are marked to assist Parties in determining the origin of tobacco products, and in accordance with national law and relevant bilateral or multilateral agreements, assist Parties in determining the point of diversion and monitor, document and control the movement of tobacco products and their legal status. In addition, each Party shall:

- (a) require that unit packets and packages of tobacco products for retail and wholesale use that are sold on its domestic market carry the statement: “*Sales only allowed in (insert name of the country, subnational, regional or federal unit)*” or carry any other effective marking indicating the final destination or which would assist authorities in determining whether the product is legally for sale on the domestic market; and
- (b) consider, as appropriate, developing a practical tracking and tracing regime that would further secure the distribution system and assist in the investigation of illicit trade.”

Article 15, § 2 (a) is a rather confusing Article, because it lists different marking or labelling provisions which do not have the same objective and which cannot have the same desired outcome, such as the domestic market label and the country of final destination label. The initial intention of this paragraph was to mention only the final country of destination, but both Canada and the US were against this proposal and the agreed final paragraph was the listing of different possible markings or labels.

Article 15, § 2 (b) has the merit to mention, for the first time, the consideration to develop a tracking and tracing system which would then inspire parties to develop such systems. The concept however, what exactly is meant by tracking and tracing became clearer only during the negotiations of the Protocol.

2.1.9.1 WHO FCTC PROTOCOL TO ELIMINATE ILLICIT TRADE IN TOBACCO PRODUCTS

According to Article 33 of the WHO FCTC, the Conference of the Parties (COP) may adopt protocols to the Convention. Only Parties to the Convention may be Parties to a protocol. The Protocol to Eliminate Illicit Trade in Tobacco Products, the first Protocol to the Convention, was adopted on 12 November 2012 at the fifth session of the Conference of the Parties in Seoul, Republic of Korea. Health, Finance, Justice and Customs officials of more than 140 Parties to the WHO FCTC took part in the negotiations. The Protocol builds upon and complements Article 15 of the WHO FCTC, which addresses the means of countering illicit trade in tobacco products, a key aspect of a comprehensive tobacco control policy.

After 20 months, 54 parties (15 EU Member States and the EU) have signed and five parties (Austria, Gabon, Mongolia, Nicaragua, Uruguay) have ratified the protocol. In comparison, 168 Parties had signed the FCTC and 23 Parties had ratified the FCTC after one year. The protocol will come into force 90 days after the ratification by 40 Parties.

An important Article of the Protocol is Article 8 on tracking and tracing, which contains specific provisions and fixed deadlines, such as the requirement for unique, secure and non-removable identification markings for unit packets of cigarettes within a period of five years and ten years for other tobacco products (see annexure 1).

Comments on tracking and tracing Article 8 of the protocol and its implementation:

- 1) Many Parties expressed their concern during the negotiations that the control of the tracking and tracing system would be delegated to the tobacco industry. For this reason, it is stipulated in §2 that the tracking and tracing system is "controlled by the Party". In addition, it was emphasized in §12 that obligations assigned to a Party shall not be performed by or delegated to the tobacco industry and in §13 that each Party shall ensure that its competent authorities, in participating in the tracking and tracing regime, interact with the tobacco industry and those representing the interests of the tobacco industry only to the extent strictly necessary in the implementation of this Article.
- 2) The Article is called tracking and tracing, but it should be noted that parties have been less interested in tracking (the monitoring of packages around the world) than in tracing (the re-creation of the route of the seized cigarettes). Some parties fear that a global, centrally managed database would be too expensive and might raise data protection concerns.
- 3) The aim of the tracing system is to secure the supply chain and to assist in the investigation of illicit trade of tobacco products. Several factors justify combating illicit trade as a priority in the European Region. Compared to other WHO regions, the European Region has the highest smoking prevalence, the highest proportion of deaths attributed to tobacco, the highest cigarette tax levels. Illicit trade in tobacco undermines tobacco control policies (such as the effort to eliminate undesired additives), as well as demand reduction policies. The availability of cheap illicit cigarettes increases cigarette consumption in Europe and thus tobacco related deaths in the future.³⁶
- 4) The FCTC protocol foresees a global information sharing focal point, but so far no feasibility studies have been undertaken or no information is available on how this global focal point would function. The FCTC secretariat hired at the end of 2013 a staff member specialized in IT to look at Article 8 of the FCTC protocol.
- 5) Unique identifiers should be secure, but no definition was provided on the meaning of secure and no discussion has taken place on the meaning of secure during the negotiations.
- 6) Article 8(4) of the protocol foresees the obligation to provide detailed information and §10 stipulates that each party shall require the further development and expansion of the scope of the applicable tracking and tracing system up to the point that all duties, and relevant taxes have been discharged. The objective of the protocol is to have information through the whole supply chain until duties are paid or other obligations discharged. The objective was not to have a tracking a tracing system including the retail level, which was considered as too complex in many countries around the world.

³⁶ FCTC Secretariat, Combating the Illicit Trade in Tobacco Products from an European perspective, text prepared by Luk Joossens at the request of the Convention Secretariat, April 2014.

- 7) Pursuant to § 3 the unique identifiers apply to all unit packets and packages and any outside packaging (packs, cartons, master cases, pallets).
- 8) No Party is prevented from going beyond the requirements of the Protocol.

2.2 THE EU TOBACCO PRODUCTS DIRECTIVES

Traceability of tobacco products has been regulated by the Tobacco Products Directive (TPD) 2001/37/EC and by the Tobacco Products Directive 2014/40/EU.

2.2.1 THE 2001/37/EC TOBACCO PRODUCTS DIRECTIVE OF 5 JUNE 2001

The Tobacco Products Directive 2001/37/EC, which *covers the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products*, has two objectives:

1. Facilitating the functioning of internal market in tobacco products sector, and
2. Ensuring a high level of public health.

The 2001 Tobacco Products Directive contained a provision for batches of tobacco products to be marked so that those products are traceable for the purposes of monitoring compliance with this Directive. Article 5, § 9 of the 2001 TPD stipulated that, "to ensure product identification and traceability, the tobacco product shall be marked in any appropriate manner, by batch numbering or equivalent, on the unit packet enabling the place and time of manufacture to be determined."

Given the importance of traceability in limiting illicit trade, this provision was further developed in the review of the Tobacco Products Directive (see below Article 15 and 16 of Directive 2014/40/EU).

2.2.2 ARTICLES 15 AND 16 OF THE 2014/40/EU TOBACCO PRODUCTS DIRECTIVE OF 3 APRIL 2014

In the 2014/40/EU Tobacco Products Directive it was confirmed that the Directive would still focus on the same objectives as the 2001 TPD, which were: (1) facilitating the functioning of internal market in tobacco products sector, and (2) ensuring a high level of public health. The main purpose of the Tobacco Products Directive is not combating tax evasion and fraud, but a better functioning of the internal market while ensuring a high level of public health, which is described in the recitals 29-31 of the Directive in the following way:

- (29) Considerable volumes of illicit products, which do not fulfil the requirements laid down in Directive 2001/37/EC, are placed on the market and there are indications that these volumes might increase. Such illicit products undermine the free circulation of compliant products and the protection provided for by tobacco control legislation. In addition, the FCTC requires the Union to combat illicit **tobacco products, including those illegally imported into the Union**, as part of a comprehensive Union policy on tobacco control. Provisions should, therefore, be made for unit packets of tobacco products to be marked with a unique identifier and security features and for their movements to be recorded so that such products can be tracked and traced throughout the Union and their compliance with this Directive can be monitored and better enforced. In addition, provisions should be made for the introduction of security features that will facilitate the verification of whether or not tobacco products are authentic.

- (30) An interoperable tracking and tracing system and security features should be developed at Union level. For an initial period only cigarettes and roll-your-own tobacco should be subjected to the tracking and tracing system and the security features. This would allow **manufacturers** of other tobacco products to benefit from the experience gained prior to the tracking and tracing system and security features becoming applicable to those other products.
- (31) In order to ensure independence and transparency of the tracking and tracing system, manufacturers of tobacco products should conclude data storage contracts with independent third parties. The Commission should approve **the suitability of those independent third parties and an independent** external auditor should monitor their activities. The data related to the tracking and tracing system should be kept separate from other organisation related data and should be under the control of, and accessible at all times by, the competent authorities from Member States and the Commission. "

The following are comments on Article 15 (traceability) and Article 16 (security features) of the 2014/40/EU Tobacco Products Directive as the first step in defining the Problem Statement for this Project:

- The Article 15 of 2014/40/EU Directive applies to nearly the whole supply chain: from the manufacturer to the last economic operator before the first retail outlet. However, the retailers are not part of the traceability obligations. In this regards, Article 15 goes further than the FCTC protocol. In the Protocol, the aim is a traceability solution that works up to the point that all duties and relevant taxes, and where appropriate, other obligations have been discharged.
- Article 15 states that a unique identifier should be applied at pack level. There is no obligation for markings on the other outside packaging, such as defined in the Protocol. However, clear reference is made to aggregation in §3: *"this obligation can be fulfilled by marking and recording of aggregated packaging, such as carton, master case or pallet, provided that tracking and tracing of unit packets remains possible."* Article 15 implies, in practice, that identifiers on the outside packaging and aggregation (parent-child relationships between different packaging units such as packs, cartons, master cases) are necessary in order to comply with its obligations.
- Furthermore, it states that unique identifiers shall be irremovably printed/affixed, indelible and in no way hidden or interrupted in any form, by means of tax stamps and price marks, or by the opening of the packet. The word "secure" is not used to define the markings, such as mentioned in the Protocol.
- While the Protocol states that the (a) date and location of manufacture, (b) manufacturing facility; (g) product description; and where available (f) the intended market of retail sale shall form part of the unique identification markings; Article 15³⁷ of the TPD states that in addition to the above the unique identifier should also include the following information: (c) the machine used to manufacture the tobacco products; (d) the production shift or time of manufacture; (f) the intended market of retail sale; (g) the intended shipment route and (h) where applicable, the importer into the Union.
- In Article 15 it states that all economic operators must record the relevant data throughout the whole supply chain, but it does not specify which marking should be used. Technical and operational details for the traceability system will be regulated by implementing acts. The Commission will, in consultation with the

³⁷ Additional legal and technical analysis will be required to clarify the precise mode of application of these existing requirements in this regard.

Member States, develop standards to be used to ensure, for instance, compatibility of the identifiers used across the EU. Those rules and technical standards will also apply to the marking, recording, transmitting, processing, storing of data and their accessibility. (Implementing acts foreseen in §11)

- The tracking and traceability data will be stored by an independent organisation, located in the EU and controlled by an auditor. *“The suitability of the third party, in particular its independence and technical capacities, as well as the data storage contract, shall be approved by the Commission. The third party's activities shall be monitored by an external auditor, who is proposed and paid by the tobacco manufacturer and approved by the Commission. The external auditor shall submit an annual report to the competent authorities and to the Commission, assessing in particular any irregularities in relation to access.”*
- “Member States shall ensure full accessibility of the data storage facilities for the competent authorities of the Member States, the Commission and the independent third party. In duly justified cases, Member States or the Commission can provide manufacturers or importers access to this information, provided commercially sensitive information remains adequately protected in conformity with the relevant national and Union legislations.”
- *“In addition to the unique identifier referred to in Article 15, Member States shall require that all unit packets of tobacco products, which are placed on the market, carry a tamper proof security feature, composed of visible and invisible elements. The security feature shall be irremovably printed or affixed, indelible and not hidden or interrupted in any form, including through tax stamps and price marks, or other elements imposed by legislation.”* Article 15 goes further than the protocol as the security feature is not an obligation in the FCTC protocol. Implementing acts will define the technical standards for the security feature and their possible rotation and to adapt them to scientific, market and technical development.
- Article 15 of the TPD defines clearly that the tobacco industry will bear the costs of the equipment necessary for the recording of the tobacco products purchased, stored, transported or otherwise handled for all operators in the trade of tobacco products. (§ 7 of Article 15).
- Article 15 does not mention the FCTC global information sharing focal point.
- The main department involved in the follow-up of Article 15 of the TPD will be DG SANCO whose task it is to guarantee the free movements of goods and to ensure a high level of public health.

2.3 ILLICIT TRADE FRAUD ARCHETYPES

While the TPD focuses on reducing non-compliant products on the internal market and reducing illicit supply for the purposes of consumer and health protection, illicit trade in tobacco also has to be seen in the wider perspective of Customs and Excise frauds. Tobacco and cigarettes lend themselves to a particular set of Customs and Excise fraud typologies, both in terms of legitimately manufactured cigarettes and illicit cigarettes. The following fraud typologies make the analogy to a Customs Union (as in the EU) with distinct internal excise and VAT regions. These fraud types can occur in both the original country of manufacture, at the border and post-border:

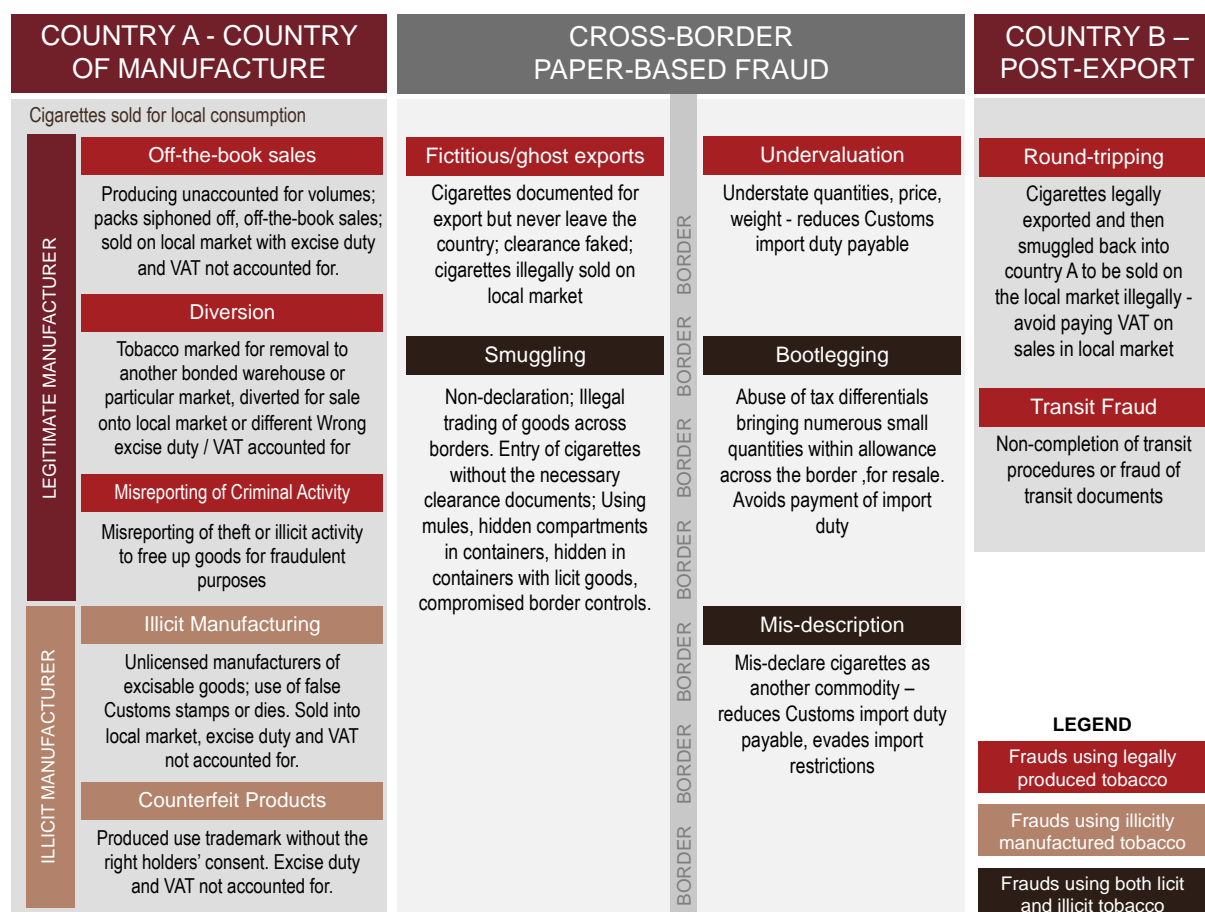


















Figure 13 - Summary of Key Tobacco Fraud Archetypes

Track and trace and other technologies that work towards securing the supply chain can work together and are suited to addressing several customs and excise fraud and illicit trade archetypes, as displayed in the following table.

It must be noted that security features and traceability functionality are closely linked and in some case co-dependent. For example, non-secure traceability could result in the tracking and tracing of illegitimate products in the case where the unique identifier from a legitimate product is replicated onto an illicit product. The security features that are incorporated into a solution ensure that only “genuine” articles are allowed to enter the traceability system.

Fraud Archetype	Definition	Trace-ability	Security Feature
Illicit manufacturing	Illicit manufacturing in which a product bears a trademark without right holders’ consent. Illegally manufactured products can be sold in the source country or smuggled into another country. Excise tax is rarely, if ever, paid on counterfeit and/or unlicensed manufacturing.		

Fraud Archetype	Definition	Traceability	Security Feature
Transit Fraud and Ghost exports	Product declared for in-transit removal to country B but kept in country A and sold in the local market. This includes acquittal fraud, which happens when documentation is provided that falsely indicates that the product has been exported (referred to as a ghost export), with the product having been sold in the local market. This may allow an unlawful reclaim or non-payment of excise duty and non-payment or refund of VAT.		
Diversion	Products are declared for consumption in one country (with taxes and duties often legitimately paid in that country), with the intention of illegally moving the products into another territory where taxes and duties would otherwise be higher.		
Illicit whites / cheap whites	Brands manufactured legitimately in one market, either taxed for local consumption or untaxed for export, and sold knowingly to traders who transport them to another country where the products are sold illegally without domestic duty paid'.		
Mis-declaration	Mis-declaration of tariff code to attract a lower rate of duty, or to avoid undue scrutiny of the consignment or mis-declaration of the end destination.		
Round-tripping	Cigarettes are legally exported to country B, and then smuggled back into country A to be sold on the local market illegally, in order to avoid paying VAT and Excise Duties on sales in the local market in Country A.		
Smuggling	The movement of goods across a Customs frontier in any clandestine manner, evading Customs control. Non-declaration (where no product is declared at port of entry) is also a form of smuggling.		
Illicit whites / cheap whites	Using smuggling, this fraud type specifically leverages brands developed and manufactured legitimately in one market, either taxed for local consumption or untaxed for export, and sold with an intention for traders to transport them to another country where the products are sold illegally without domestic duty paid'.		
Under-valuation	Typically incorrectly declaring weight, quantity or value, and invoices differing from the bill of lading, in order to minimize the payment of import duty and VAT.		






Fraud Archetype	Definition	Traceability	Security Feature
Under-declaration of production volumes	Legitimate manufacturer under-declares production volumes, siphoning off some of their production and selling the cigarettes off the books, in order to avoid paying excise duties, VAT and subsequently income tax.		
 Minimal  Partial  Full			

Table 6 - Summary of Tobacco Fraud Archetypes

2.4 DEFINING THE PROBLEM STATEMENT

Illicit and unregulated tobacco products can further harm the public and increase tobacco consumption, undermining the objectives of EU Health Policies³⁸. These non-conformant tobacco products do not adhere to manufacture, formulation, packaging and pricing requirements intended to reduce harm and curb tobacco consumption. Without adequate controls in place, these illicit products are able to enter and circulate in the EU internal market to be consumed by the public.

To support the tobacco control policies of the Member States a solution is required that will support Member States in determining the market legitimacy of tobacco products, in order to protect the internal market from non-conformant products.

All stakeholders, if possible including consumers, should be provided a mechanism to authenticate that tobacco products available for purchase are legitimate.

2.4.1 TRACEABILITY

To address this problem, the following critical success factors have been identified from an understanding of the background and context of the problem statement. The track and trace solution for tobacco products should:

- 1 Ensure each pack is marked with a unique identifier; (Article 15, §1)
- 2 Provide an accurate mechanism for recording the movement (tracking) of tobacco products from the point of manufacture to the last economic operator before retail; (Article 15, §5)
- 3 Support the concept of aggregation, wherein the items within a container (carton, master case, pallet etc.) are recorded, and a unique identifier is then assigned to the container and used as the basis to record the movement of the container (with its contents) through the distribution chain. This parent-child relationship can record the hierarchy between packs and cartons, cartons and master cases, and master cases and pallets; (Article 15, §5)
- 4 Store data independently (not by the tobacco industry); (Article 15, §8 and recital 31)
- 5 Ensure that the systems used for the unique identifier and the related functions are fully compatible with each other across the European Union; (Article 15, §11b)

³⁸ Recitals 10 to 13 of the TPD reflect its scope to be broader than the quantity control and also covers the fight against undesired additives.

6	Protect confidentiality and safeguard that decoding and full access to the data storage facilities is limited to authorised authorities and only exceptionally in duly justified cases to the tobacco industry under restrictive conditions; (article 15, §8)
7	As far as possible, be compatible with current tobacco production, packaging and the trade environment to minimise the impact on tobacco production taking into consideration production speeds, equipment, etc. (internal market proportionality obligations);
8	Uphold respect for data protection as specified in the EU legal framework (Directive 95/46/EC); (Article 15, §10)
9	Be resistant to manipulation. This includes physical measures such as providing that marks are irremovable and indelible, but also solution design considerations such as non-predictability of unique identifier codes, traceability data reconciliation against other data sources, safeguards against traceability being accessed / used by unauthorised parties; (Article 15, §1)
10	Enable Member States and EU authorities to monitor and survey the market as per respective mandates; (general aim of Article 15 and recital 29)
11	As far as possible, utilise solution components currently being used in a commercial supply chain environment and avoid unnecessary burden for business and/or authorities (Impact assessment considerations).

Table 7 - Traceability Solution Critical Success Factors

A worldwide tobacco traceability solution would be favourable considering the requirements of the FCTC protocol and the objective of reducing illicit trade. A solution for the EU should therefore not preclude any international solution.

In addition to the above critical success factors, cost implications will be considered. However, this will form part of the Cost Benefit Analysis in the subsequent deliverable.

2.4.2 SECURITY FEATURES

In review of the context and requirements, the following critical success factors have been identified for the security features to be applied to tobacco products:

1	Provide a reliable mechanism to authenticate the legitimacy of a tobacco product; (Article 16, §1)
2	Have overt elements which provide the modicum of authentication by the consumer without requiring specialised equipment / devices; (Article 16, §1 and impact assessment considerations)
3	Must be tamper proof and irremovable; (Article 16, §1)
4	Ensure that covert elements are accessible by authorised persons and protect commercially sensitive data, if necessary; (article 16, §1 and impact assessment considerations)
5	Provide court-admissible forensic evidence of security feature authentication;
6	As far as possible, be compatible with the current tobacco production, packaging trade environment and existing tax regimes and avoid unnecessary burden for business and/or authorities (internal market proportionality obligations).

Table 8 - Security Feature Critical Success Factors

In addition to the above critical success factors, cost implications will be considered. However, this will form part of the Cost Benefit Analysis in the subsequent deliverables.

2.5 ASSESSMENT OF KEY FUNCTIONAL REQUIREMENTS

2.5.1 STAKEHOLDER REQUIREMENTS MATRIX

The traceability and security feature system for tobacco products will be beneficial to a number of stakeholders.

Table 9 - Stakeholder mapping to Article 15 & 16 Benefit

Stakeholder	Article 15/16 Benefit
Law Enforcement (Police, Customs, Tax and Public Health)	<ul style="list-style-type: none"> All products marked with a unique identifier. In combination with a database this provides information from the manufacture to the first retail outlet which is accessible for law enforcement officials see Article 15 (8) Unique identifiers are indelible and security features are tamper proof All products intended for the EU market carry tamper-proof security feature composed of visible and invisible elements Information is stored in a database which is accessible for law enforcement officials see Article 15 (8)
OLAF	<ul style="list-style-type: none"> Economic operators involved in the trade of tobacco products, from the manufacturer to the last economic operator before the first retail outlet, record the entry of all unit packets into their possession Information on the product through the supply chain is stored in a database which is accessible for OLAF officials see Article 15 (8)
UNODC	<ul style="list-style-type: none"> Depending on administrative cooperation arrangements, the supply chain data could indirectly be of use to UNODC and WCO efforts (with the possibility to provide this information through a request process agreed by the EU Commission and Member States. All products intended for domestic market carry tamper-proof security feature composed of visible and invisible elements
WCO	
WHO FCTC Secretariat	<ul style="list-style-type: none"> Provide a foundation for EU Member States to participate in the FCTC global information sharing focal point. Traceability of tobacco products to combat illicit tobacco products
DG SANCO	<ul style="list-style-type: none"> All products intended for domestic market carry tamper-proof security feature composed of visible and invisible elements to guarantee regulated tobacco products. Traceability of tobacco products to combat non-conformant and/ or illicit tobacco products
DG TAXUD	<ul style="list-style-type: none"> Economic operators involved in the trade of tobacco products, from the manufacturer to the last economic operator before the first retail outlet, record the entry of all unit packets into their possession. Information on the product through the supply chain is stored in a database which is accessible for DG TAXUD officials and the customs administrations of the Member States in the context of the Common Risk Management Framework - see Article 15 (8)".
Consumers	<ul style="list-style-type: none"> All products intended for domestic market carry tamper-proof security feature composed of visible and invisible elements
Industry	<ul style="list-style-type: none"> All products intended for domestic market carry tamper-proof security feature composed of visible and invisible elements

The functional requirements related to the security feature have dual stakeholder groups – enable both consumers and authorities to authenticate legitimate products. Given the context of tobacco control, it is envisaged that would comprise four different cases:

- **Consumer Level:** Quick reflex validation to verify if a tobacco product is legitimate using the visible (overt) security feature outlined in the TPD. An example would include a Consumer validating a tobacco pack at the point of sale before the sale transaction is concluded.
- **Industry:** The tobacco industry economic operators would benefit from the ability to differentiate licit and illicit tobacco products to protect the distribution chain from contraband (overt and semi-covert security features).
- **EU or Member State Authorities:** Deliberate authentication of a tobacco product to verify its legitimacy by using the invisible (or covert) security feature. An example would be an EU Customs official authenticating tobacco products crossing the EU border into the domestic market.
- **EU or Member State Enforcement / Investigation Authorities:** Security feature used as a means to collect court admissible evidence as to the legitimacy of a tobacco pack to support investigations (and possibly prosecution).

Building on the above table the matrix below presents the functional requirements that have been derived from Article 15 and 16 mapped against each of the stakeholders directly involved in the tobacco traceability and authentication solutions.

Table 10 - Identification of Key Functional Requirements of Respective Stakeholders

Key Functional Requirement	Stakeholder							
	Law Enforcement	Customs Admin.	Tax Admin.	OLAF	DG SANCO	DG TAXUD	Consumers	Industry
Security feature available to authenticate tobacco products as legitimate	X	X	X	X	X	X	X	X
Verification of the information that is part of the unique identifier (origin, destination etc.)	X	X	X	X	X	X		
Accessibility to centralised database for risk profiling, assessment & cases of investigations	X	X		X		X		
Access to real-time movement information on tobacco consignments	X	X	X	X		X		
Accessibility to Court-admissible evidence	X	X		X				
Tamper-proof security features to prevent reuse of identifier onto illicit products	X	X	X	X				
Provide support for FCTC Parties to analyse and combat illicit tobacco trade	X			X				
Recognition of the difference between licit and illicit tobacco products	X	X	X	X	X	X	X	X
Traceability and alerting of products which do not comply with national or EU legislation	X	X		X	X	X		
Facilitate investigations in the case of tax fraud	X	X		X		X		
Ability to identify and report illicit tobacco products	X	X		X	X	X	X	

From the above requirements, it is apparent that functions related to tobacco traceability, apart from assisting the authorities in meeting the objectives of the TPD may meet a number of other functional requirements.

In the following table, the key functional requirements of the external stakeholders that may have an interest in the tobacco traceability and authentication solution are considered.

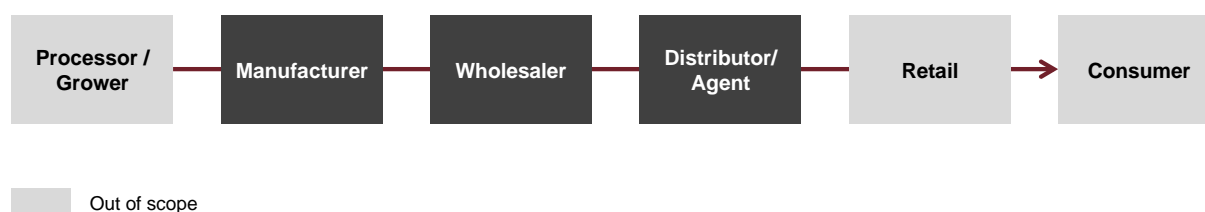
Table 11 - Identification of Key Functional Requirements of Respective Stakeholders

Stakeholder Key Functional Requirement	Interpol	UNODC	WCO	WHO FCTC Secretariat
Security feature available to authenticate tobacco products as legitimate	X		X	
Verification of the information that is part of the unique identifier (origin, destination etc.)	X			
Accessibility to centralised database for risk profiling, assessment & cases of investigations				
Access to real-time movement information on tobacco consignments				
Accessibility to Court-admissible evidence				
Tamper-proof security features to prevent reuse of identifier onto illicit products				
Provide support for FCTC Parties to analyse and combat illicit tobacco trade				X
Recognition of the difference between licit and illicit tobacco products	X			
Traceability and alerting of products which do not comply with national or EU legislation		X		
Facilitate investigations in the case of tax fraud	X			
Ability to identify and report illicit tobacco products				

3 THE TOBACCO SUPPLY CHAIN IN THE EUROPEAN UNION

This section looks at the tobacco supply chain in the European Union (EU) to provide context for analysis of tobacco traceability and authentication solutions in this market. The main actors and scope of the solution are identified, followed by a brief analysis of the primary tobacco distribution chain flows. Then a summary of key industry considerations relevant for any traceability or authentication solution operating in this domain is presented.

The TPD indicates that the traceability and security feature requirements must be met by all tobacco products *which have either been manufactured in the EU or are imported into the EU to be placed on the EU market*. Additionally, reference is made to the responsibilities for tracking the movement of tobacco products from the manufacturer until the last economic operator before the retail outlet. The following supply chain illustration shows the scope within the context of the tobacco supply, manufacture and distribution chain.



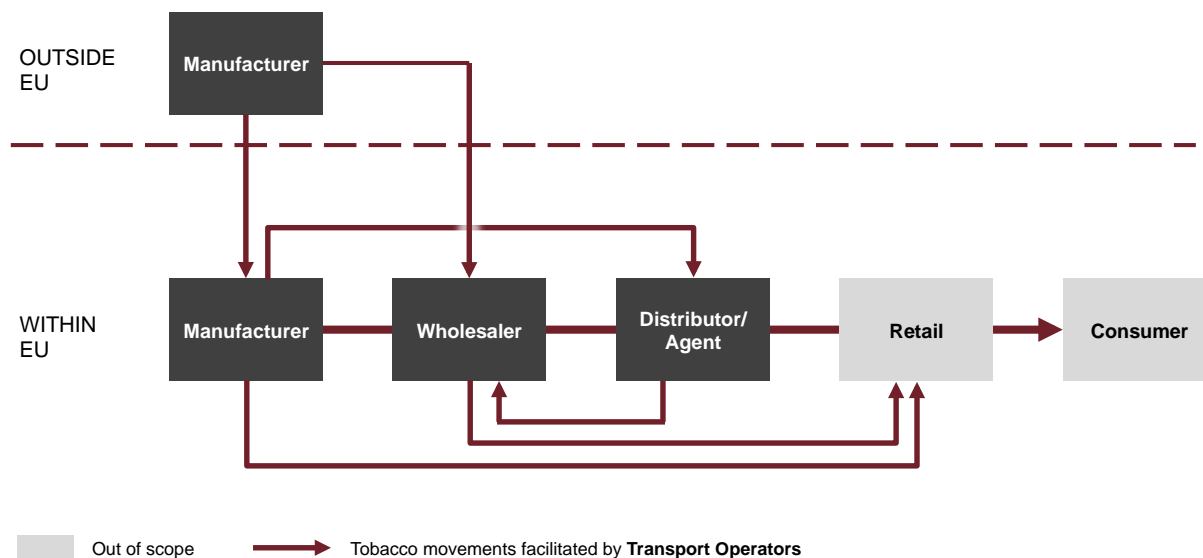
The key parties identified in this end-to-end supply chain include:

- **Processor / Grower** - refers to individuals and/or companies that either farm, trade leaf and process tobacco, for use by the industry;
- **Manufacturer** - companies that produce unmanufactured tobacco and manufacture tobacco products;
- **Wholesaler** - entities that mass distribute tobacco, be it to their distributors/agents or to retail outlets directly;
- **Distributor/Agent** - the major wholesaling companies have local agents (normally small businesses) that sell and deliver tobacco products to retail shops;
- **Retail** - point where tobacco is sold to the end consumer; and
- **Consumer** - those who actually buy and consume the product in its final shape or form.

The tobacco growers, processors, and retailers are considered out of the scope of the traceability solution. It should be noted that although the **Consumer** and **Retailer** are shown as out of scope in terms of the traceability solution, they are both seen as stakeholders and users of the security features. It is envisaged the consumer will be the primary user of the overt (visible) security feature to be applied to tobacco packs to provide a mechanism to authenticate that the product is legitimate.

3.1 OVERVIEW OF THE TOBACCO SUPPLY CHAIN

The number of possible combinations of supply flows applicable to the tobacco business is diverse, especially when commercial exceptions such as damaged, returned and repackaging of goods occur. However, the main distribution chain flows are illustrated below.



Some variance can exist within the supply chain depending on a series of circumstances:

- Manufacturing facilities may themselves be importers and/or exporters: this is prevalent with the larger tobacco operators, where specialization of some factories apply to given brands (or to cut fillers or filters, for instance), where import and export activities take place. This tobacco can either be sold and consumed within the country of first manufacture, or exported to another country;
- The above can also apply for wholesalers, where their size and network allows them to import from a given manufacturing country and then trade in their domestic country; and
- The relationships between distributors are recursive and the tobacco products may transfer ownership through multiple distributors or agents before reaching the final retail destination.

An important implication of the tobacco distribution chain is recognition that while the tobacco manufacturer may be exclusively manufacturing and shipping tobacco products, as the goods move through wholesalers and distributors through the distribution chain, increasingly the operators will be dealing in other goods besides tobacco. For example, consider the distributors supplying supermarkets and chain stores; it is likely that tobacco products will only be a fraction of the vast array of products that are being managed on a daily basis. Therefore careful consideration will be required of the requirements imposed by any traceability solution operating in this domain.

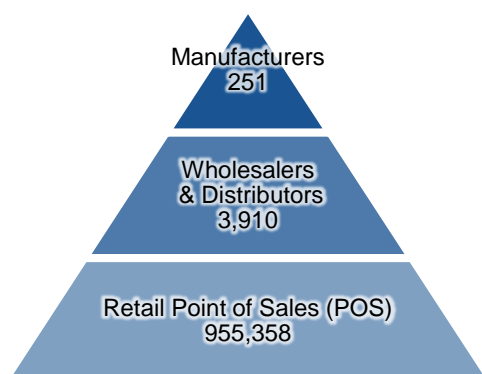


Figure 14 - Tobacco Supply Chain Hierarchy (Data Source: Nomisma 2012)

The EU Tobacco distribution chain is very broad. According to NOMISMA (2012) there are 251 Manufacturers operating some 362 tobacco manufacturing facilities within the EU.

These products are distributed to the retail environment through a network of 3,910 wholesalers and distributors.

In total, just under 1 million point of sale outlets stock and retail tobacco products. In addition, tobacco products are also made available through an estimated network of 671,000 vending machines.

3.1.1 THE CROSS-BORDER MOVEMENTS OF TOBACCO GOODS

The tobacco traceability solution will also need to consider tobacco product movements into, within and out of the EU.

The matrix below illustrates the main movement types: The vertical axis plots the origin of the goods, while the horizontal axis plots the destination of the goods.

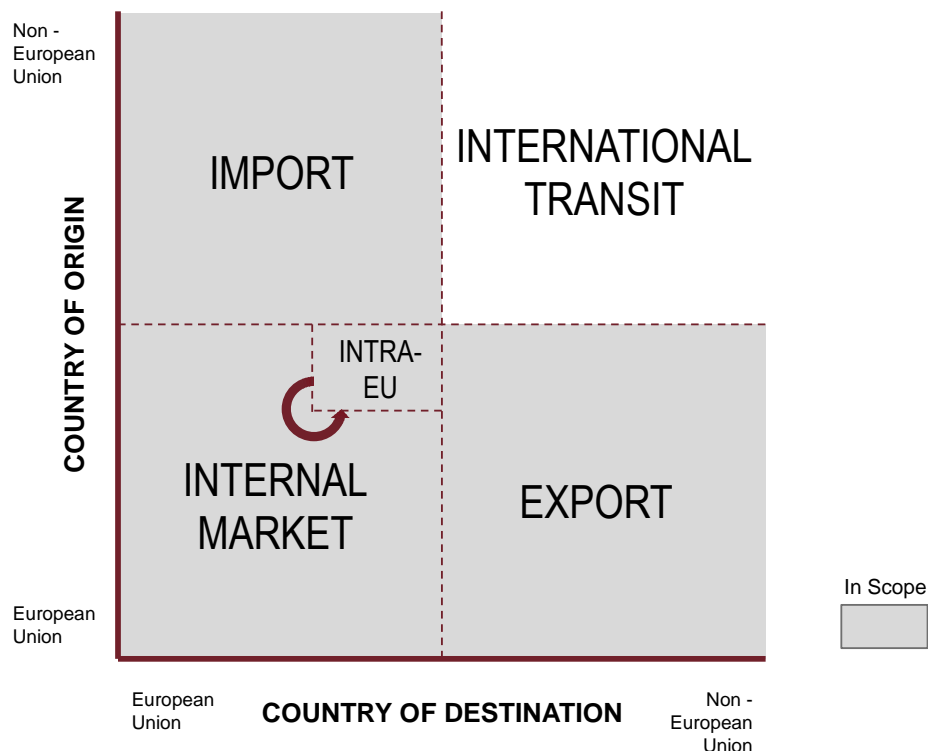


Figure 15 - Nature of Tobacco Trade Flows from an EU Perspective

Therefore, the traceability solution needs to consider:

- **Internal Market:** The method tobacco products produced within the EU community are marked with unique identifiers and security features and tracked within the Member States;
- **Imports:** The marking of tobacco products manufactured outside of the EU with unique identifiers for traceability and security features for authentication purposes, prior to the goods being made available on the internal market. Further, there may be consideration as to whether products are marked at the time of manufacture in the foreign country, or marked at the time of import (or both);
- **Exports:** The application of unique identifiers for traceability purposes for goods manufactured in the EU, where those tobacco products are intended for placement on a foreign market outside of the EU; and
- **Intra-EU:** Where tobacco products originating in one Member State are transported for placement on the internal market in another Member State.

International Transit is considered out of scope both in terms of traceability and for application of security features, as these goods are neither manufactured in the EU, nor intended for placement on the EU internal market.

3.1.2 THE INTERNAL MARKET IN THE EU

The EU tobacco market is important globally, accounting for almost 20% of cigarettes consumed by volume of the global market outside of China³⁹. (China alone is responsible for 38% of the global tobacco consumption).

The tobacco industry includes the manufacturing of all tobacco products – particularly cigarettes, fine cut tobacco, cigars, pipe tobacco, chewing tobacco, snuff and Swedish snus. Of these, cigarettes are by far the most consumed tobacco product.

The value of tobacco sales in the EU market has grown at a compound annual growth rate of ~4% over the past 5 years. The financial crisis adversely impacted the tobacco market in 2009-2010, but has since recovered.

However, while the value of the EU tobacco industry has grown, the actual volumes of tobacco products have been declining. In 2011 the legitimate tobacco market was an estimated 585 billion cigarettes in the EU, or approximately **30 billion cigarette packs**. This figure has been declining slightly over the past 5 years at a compound annual rate of 3.4%. The market is quite concentrated amongst the larger Member States: according to Euromonitor; the eight largest EU cigarette markets represent 77% of the total EU tobacco market.

Retail of cigarette products in the EU is generally either at tobacco pack or tobacco carton level. A tobacco pack contains at least 20 cigarettes and a tobacco carton contains 10 packs (or 200 cigarettes).

For transport, these tobacco cartons are bulked into mastercases of variable sizes and contents (normally 52 cartons). Pallets of mastercases are the usual form for warehouse storage and container transportation, where a 40' container would carry around 10 million cigarettes.

3.1.3 IMPORT AND EXPORT

In 2011 total tobacco imports into the Internal Market by Member States amounted to some € 250 million (0.02% of total trade imports). The top 5 importing Member States (by value) are provided in the table below.

³⁹ Euromonitor, 2012.

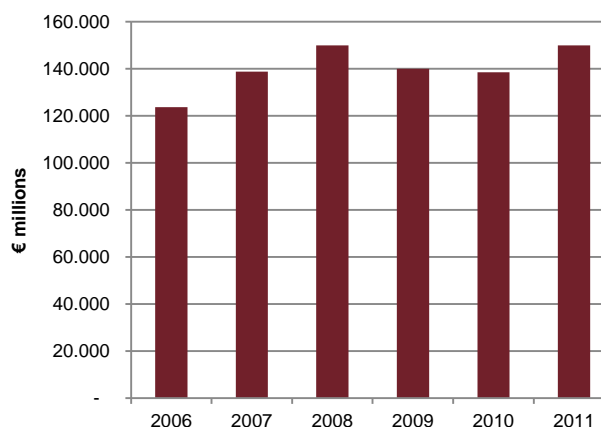


Figure 16 - Tobacco Sales in the EU (Value by retail prices)
(Source: Euromonitor, 2012)

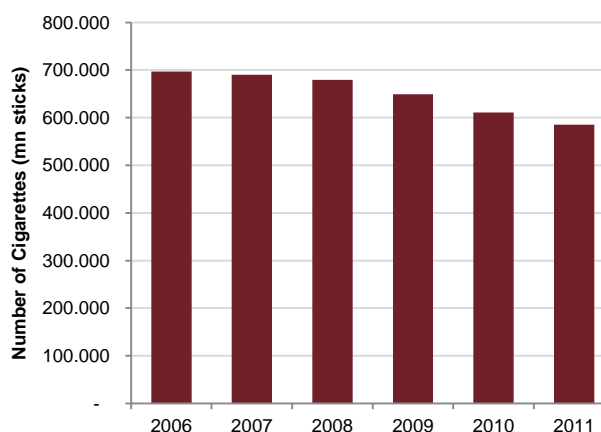


Figure 17 - Tobacco Product volumes consumed in the EU (Source: Euromonitor, 2012)

#	Country	Import Value (€'000)	% of Total Extra-EU27
1	Spain	49,361	20%
2	France	46,492	19%
3	Germany	46,248	18%
4	Belgium	36,993	15%
5	United Kingdom	9,332	4%

Table 12 - Top 5 Tobacco Importing Member States (Data extracted from Eurostat)

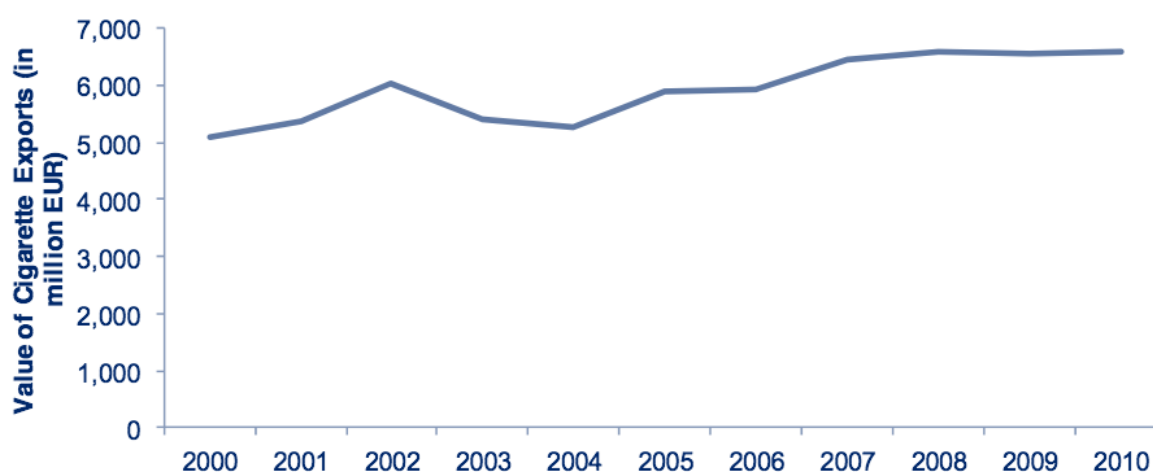
In contrast, the value of exports of tobacco products extra-EU27 were **almost six times greater** than imports, and totalled € 1,442 million (0.10% of total trade exports).

#	Country	Export Value (€'000)	% of Total Extra-EU27
1	Germany	436,390	30%
2	France	192,805	13%
3	Bulgaria	150,930	10%
4	Greece	108,075	7%
5	Poland	104,012	7%

Table 13 - Top 5 Tobacco Exporting Member States (Data extracted from Eurostat)

3.1.4 INTRA-EU TRADE

The value of tobacco products between Member States within the EU is substantially larger than the flows of imports and exports with non-EU trading partners. For 2010, the overall value of cigarettes traded within the EU was € 6.5 billion, representing ~5% of all cigarettes consumed within the EU. The trend shows that the value of tobacco products being transited within the community has been increasing over the past 10 years.

Figure 18 - Value of intra-EU trade of cigarettes (2000-2010)⁴⁰

⁴⁰ Matrix Report, 2013. Note: Data are not available for all of the 2000-2010 period for Malta, Slovakia, Slovenia, Cyprus, Hungary, Romania and Poland.

3.2 SPECIAL INDUSTRY CONSIDERATIONS

In addition to the above, the following issues should also be considered when establishing requirements for track and trace within the industry, including:

- Different sizes/dimensions of manufacturing facilities in the relevant EU countries – that could lead to limited or otherwise relevant investment of companies in machinery and in production control application software;
- The need to mark significant numbers of individual packs in a short period of time (equipment line speed features have to respond to such requirements, so the TPD terms are adhered to), could represent difficulties to coping with production line maintenance activities and other non-foreseen events, such as line stoppages;
- Exceptions, such as refunds, have to be taken into consideration – when a given wholesaler cannot sell, due to loss through fire, theft or other unexpected event, “remove without deleting,” packs from the distribution chain needs to be recorded; and
- Repackaging activities occur, particularly from wholesaler to the distributor/agent, and then possibly at the retail outlets. Again, these operations must be recorded so as to ensure the end-to-end integrity of the trade flow.

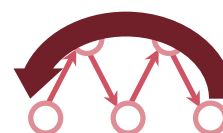
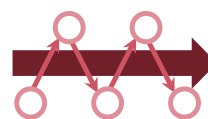
4 PRINCIPLES OF TRACEABILITY AND AUTHENTICATION

4.1 DEFINITION AND COMPONENTS OF A TRACK AND TRACE SYSTEM

Supply chains, transport and logistics today have evolved into a high-technology industry. Distribution is no longer simply about moving an item from point A to point B, but instead involves global, complex processes based on intelligent systems for sorting, planning, routing, and consolidation that support fast and efficient transportation. Concepts such as just-in-time manufacturing now require scheduling down to the minute; industries are dependent on time sensitive deliveries and commerce is dependent on tracing products throughout the supply chain or transport network.

So **what is Track and Trace?**

- **Tracking** is the concept of marking products with a unique identifier so they can be monitored from the point of production up to the point of sale to the customer, including each step of the process, creating a time and location history for every step.
- **Tracing** is the ability to identify the past or current location of an item. Where an item is intercepted, tracing allows you to verify the products route back to its origin, and allows you to retrieve a specific product's time and location history.



These two concepts combine to enable **traceability**. The International Organization for Standardisation (ISO) defines traceability as the "ability to track a product or component forward through specified stages of the supply chain to the user, and trace back the history, application or location of that product or component".

NOTE

Where "Track and Trace" can differ from "Traceability"

It is important to understand that there is another concept of traceability that differs from the concept of track and trace referred in the present study which is sometimes referred to as "metrological traceability". One definition of this concept used by the National Institute of Standards and Technology (NIST) goes as follow:

*"... Property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty"*⁴¹

Making the distinction is important, especially in the field of public health where the two notions are sometimes found together. An example of this is the current EU effort to regulate the use of pesticides and diminish the presence of residues by establishing a comprehensive set of regulations for the traceability of chemical substances used in manufacture and use of pesticides. The laboratories in charge of checking the compliance with maximum residue levels (MRLs), analytical quality control and validation procedures are entities that are dealing with metrological traceability.⁴² On a broader scale, the Codex Alimentarius Commission is also dealing with the uncertainty that sampling brings in the equation for the traceability of food and feed

⁴¹ JCGM 200:2008, International vocabulary of metrology-Basic & general concepts & associated terms (VIM 3rd Edition, 2008).

⁴² SANCO/12571/2013 19 November 2013 rev. 0, Guidance document on quality control and validation procedures for pesticide residues analysis in food and feed

As an example, consider a track and trace solution provided by a postal service / courier organisation:

- Each parcel is assigned a unique number that is applied on the label attached to the parcel.
- As the parcel moves through the transport network to its destination, important events are recorded by the logistics system at each stage, such as when the parcel arrives at a postal sorting centre, or is dispatched on an aircraft.
- The **customer is able to track the location** of the parcel at any stage and see how close it is to reaching its destination.
- The **courier organisation can trace the route and time taken** to deliver the parcel and identify any anomalies or improvement areas.

In the area of logistics, track and trace systems have become invaluable to provide consignors, transporters and customers with tracing information of the movement status of goods.

There are three fundamental components that together enable a traceability system: (1) Item Identification, (2) Data Capture and Storage, and (3) Data Sharing / Exchange.

These fundamental building blocks of any track and trace system are described further in the following sections.

4.1.1 ITEM IDENTIFICATION

In order for an item's movement to be tracked, it needs to be uniquely identifiable. Product serialization (or mass serialization) is the process used by manufacturers to assign and mark each of their products with a **unique identifier**.

This unique identifier must be one of a kind. If two different items are erroneously marked with the same identifier, the system will have no way to determine which is which, and the logistic event history would suggest one product was in two different places at the same time. The design of the codes therefore needs to consider the volumes of products in the market, and their active duration in the distribution chain in order to ensure that codes are unique.

There are several technologies and methods available for serializing products; selecting a method needs to consider materials and packaging of the product, level of security required, how the products will be tracked (human readable, machine readable or both), standards (proprietary or open), and cost. Some examples of these marking technologies include:

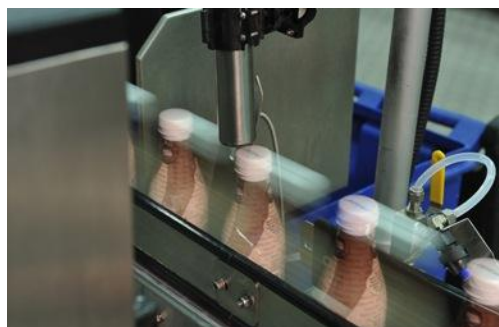


Figure 19 - Unique numbers are applied to every item and allows them to be tracked through the supply chain
(Image Source: Videonet.com)

Alphanumeric Codes

A human readable combination of numbers and digits applied to the packaging. Machine readability can be problematic making this unsuitable for medium-to-high volume scanning / verification applications.

S-1F79C464-40C1-45B

1D Barcode

Graphic representation of a unique code using structured combination of white and black bars. Highly machine-readable (most cases irrespective of orientation) and often combined with a human readable component as a failsafe should the barcode be damaged or result in errors when reading.



RFID and NFC Tags

These machine-readable tags use radio waves to communicate with a reading device. The tags contain an electronic chip that can store electronic data. The radio waves emitted by the tag-reading device powers the chip, allowing data to be transmitted wirelessly, even where there is no line-of-sight (with some restrictions) Radio Frequency Identification (RFID) has become more pervasive & allows 1-way communication of data from multiple tags to a single reader up to a 1m distance. Near Field Communication (NFC) is a new variation of RFID that allows 2-way communication between the reader and a single tag, but only up to (10cm). Pricing has become more competitive, but remains relatively high compared to other marking methods.



2D Barcode

Data matrix and QR Codes are examples of 2D bar codes that improve the amount of embedded data that can be stored, compared to the 1D barcode. 2D barcodes also potentially offer improved resilience where data can still be read where part of the barcode is damaged / destroyed. These barcodes are machine-readable only. Several ISO/IEC standards cover the data matrix considered to be in the public domain⁴³. While data encoded in a 2D barcodes may be in a proprietary format, the GS1 standard using syntax of data field identifiers (application identifiers) has emerged as a prevalent standard.



For tobacco packs, Alphanumeric Codes and Barcodes (1D and 2D) can be applied using a number of direct marking technologies including continuous inkjet, thermal inkjet, or laser. These may have some implications in terms of the tobacco pack material where these are applied (e.g. inkjet will require an area of the pack that is free of varnish, whilst laser is often applied to an area of dark printing on the pack). Alternatively, the markings may be applied to a label (in effect a transport mechanism), which may then be applied to the pack using a label applicator installed on the production line, or it can be applied manually (for low volume or low-level of automation manufacturers).

The second component of a track and trace solution is the mechanism by which logistic events are captured and supported by a central repository that ensures these captured events are stored.

⁴³ ISO/IEC 16022:2006 – Information technology – Automatic identification and data capture techniques – Data Matrix bar code symbology specification; ISO/IEC 15415:2011 – Information technology – Automatic identification and data capture techniques – Bar code symbol print quality test specification – Two-dimensional symbols; ISO/IEC 15418:2009 – Information technology – Automatic identification and data capture techniques – GS1 Application identifiers and ASC MH10 Data Identifiers and Maintenance; ISO/IEC 15459 – Information Technology – Unique Identifiers

4.1.2 DATA CAPTURE

As a product moves through the distribution chain, a track and trace “event” is captured at each stage that, amongst other things, records the location, date and time of the event. Several event types are possible and include physical movements, commercial transactions (transfer of ownership such as invoices or returns) or item verifications (recording that the item is still in the same location as reported previously, typically during a stock take / count).

These events are captured using several types of reading devices that include:

- Handheld devices used to read the unique identifier;
- Fixed mount scanners which read passing items (e.g. reading of items on a production line conveyor belt, or RFID tags passing through a gate);
- Mobile computing devices equipped to read the unique identifier of items in the field (e.g. scanning of an item at a Customs port of entry).

THE CENTRAL TRACK AND TRACE REPOSITORY

A central repository stores and records these track and trace events as they occur in the distribution chain, from the time the goods are marked, up to the point they are no longer monitored, enabling a full history of each individual item to be recorded.

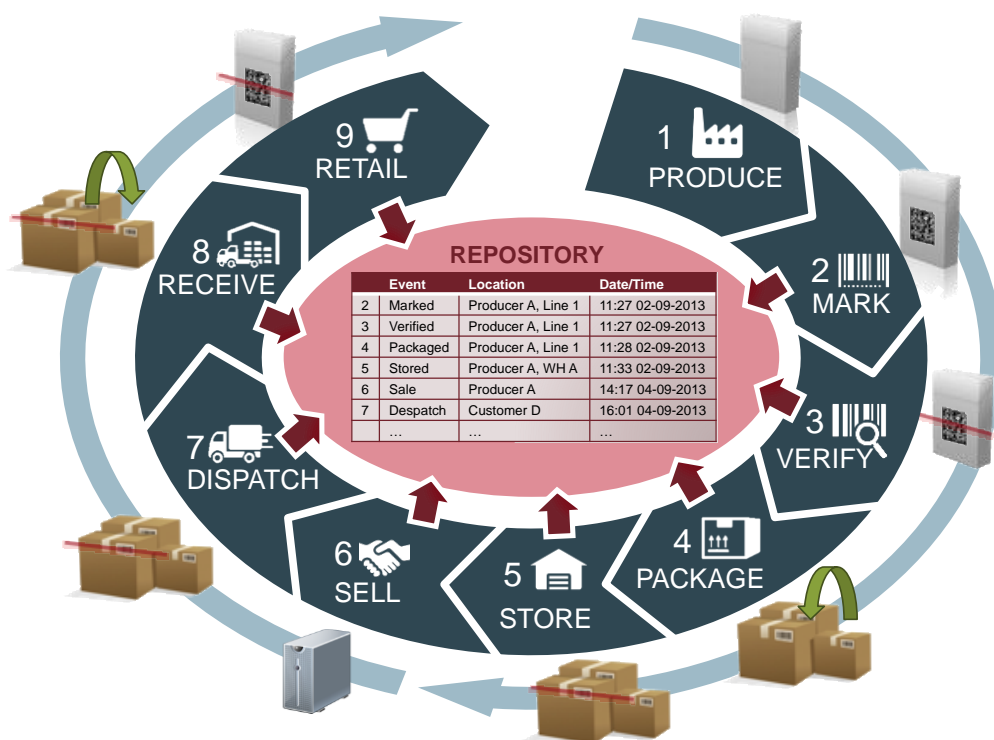


Figure 20 – Each logistic event at each stage in the distribution chain is recorded in the central repository

In the example illustrated in Figure 9 above, the central repository records track and trace events. Until the product is marked, there is no unique identifier for the item. Therefore, the traceability of the item starts from this point (item 2), and subsequent events are captured as the product moves through the distribution chain, and include:

- 2 The exact time, date and location that the item was marked with its unique identifier and when its traceability record was created;

3	Successful verification of the mark that was applied. Often this verification takes place on the production line immediately after the mark is applied as a quality control measure;
4	Aggregation events where a marked item may be placed into a second layer, or even third layer of packaging (e.g. 10 cigarette packs placed into a carton, and 50 cartons into a master case). To maintain integrity of the track and trace solution, another unique identifier will be applied to this packaging and associated with the record of the contents;
5	Warehousing of items as goods are checked-in and checked-out of storage facilities;
6	Commercial events such as where legal transfer of ownership / status occurs;
7	Repackage events where products may be repackaged to prepare a consignment for shipping and despatch by the seller (and in the process, change to the aggregation relationships needs to be recorded as the item is taken from an existing container, and moved into a new container);
8	Receipt of the Goods by another party (the purchaser);
9	Status of goods that are made available for retail (end-point of tracking events).

DIFFERENT MODELS FOR STORING TRACEABILITY INFORMATION

The above example is illustrated using a single central data repository that stores all the events related to a particular product. However, for some industries the implementation of a centralised model with a single repository may be difficult or undesirable, and there are several traceability information storage models that have been proposed as potential alternatives (e.g. one-up / one-down, decentralised and a distributed network model). These are discussed further in 4.4 below.

THE PRINCIPLE OF AGGREGATION

Aggregation allows the identification of each of the items within a container to be recorded, and associated with a unique identifier that is then assigned to the container. The unique identifier on the container can then be used as a basis to record the movement of the container (with its contents) through the distribution chain. This parent-child relationship can record the hierarchy between packs and cartons, cartons and mastercases, and mastercases and pallets

As an example, a mastercase may be received into a warehouse by scanning the code on the mastercase only. From this event, aggregation information stored in the repository will enable the determination that all 50 cartons of cigarettes contained within the mastercase have now been received at that warehouse facility, and in turn each of the 500 individual packs. By supporting this recursive logical hierarchy of grouping items within a container means logistic events can be recorded at the highest container level, rather than having to scan and receipt all 200 items at the lowest unit level.

By supporting aggregation, a traceability solution would similarly also need to have a mechanism to record unpacking / repacking operations when items are "disaggregated". As the item is unpacked from the original parent container, and repackaged into a new

container, the disassociation of the unique identifier with the 1st container, and association with the 2nd container would need to be recorded.

4.1.3 DATA SHARING

Recording track and trace events across an entire distribution chain means events may be captured by different organisations using different systems. To achieve its objective, a traceability solution therefore needs to include a way for all this event information to be accumulated to support tracing queries and supply chain oversight.

Pioneered by the RFID industry, several industry standards have evolved relating to the marking methods used, and the capture, storage and sharing of track and trace events. Because of these standards, it's possible for the one organisation acknowledging receipt of goods to publish a track and trace event that can be stored in the host organisation's central repository. Of particular interest in the domain of data reporting and sharing for traceability solutions is the Electronic Product Code Information Service (EPCIS), a technical standard maintained and promoted by GS1.

Part of the non-profit industry organisation GS1, EPCIS provides a data model and interface specification for product movement events of uniquely identified objects in general. The technical standards were originally developed for the RFID industry, however this data model has become a defacto industry standard for recording supply chain events. These standards and certified event repositories also allow interoperability between systems sharing track and trace information. As at October 2014, GS1 was currently in progress of having the EPCIS standard recognised by the International Organization for Standardization (ISO).

Organisations of relevance in the domain of traceability solutions and data sharing:



GS1 has the most widely used global standards to improve the efficiency of supply chains globally across sectors. This includes standards for barcodes, data-matrices and unique product identifiers. GS1, through its EPCGlobal product, also proposes a data model for product movement events of uniquely identified objects in general. Whilst originally developed for the RFID industry, this data model has become a standard for recording supply chain events. These standards and certified event repositories allow interoperability between systems sharing track and trace information.



ISO currently has several standards relevant including use of unique identifiers for traceability solutions, methods for encoding a unique identifier into a machine readable code (such as data matrices). Further, currently in progress is the review and recognition of GS1's proposed EPCIS technical standards.



OASIS has developed and promotes a number of open standards relating to inter-system messaging and system security. In the context of a track and trace system, supports for open standards increases the interoperability with other systems and is essential in a domain where system integration with public and private information systems is critical.



European Interoperability Strategy (EIS) is a programme of the European Commission; one of the key clusters of this Strategy is the development of a joint vision on interoperability architecture. Any technical solution proposed for tracking and tracing systems implemented in the EU should meet the architecture guidelines proposed by EIS for domains where Member States share a common interest.

4.2 THE AUTHENTICATION OF LEGITIMATE TOBACCO PRODUCTS

Commercial track and trace solutions primarily provide efficiency, traceability and customer service benefit. There is often limited incentive for the system to be manipulated by manufacturers or parties within the distribution chain. However, traceability alone is not sufficient for high risk, sensitive and government regulated products where there are incentives for criminals and fraudsters to attempt to manipulate and compromise the system to their own advantage.

As a means to **detect and combat attempts by criminals to manipulate the system**, traceability solutions often include additional security features. This means that authorities, supply chain actors, and consumers need, in addition to traceability provided by track and trace, a method to authenticate that the product and / or markings are genuine.

Authentication is the process of determining whether someone or something is, in fact, who or what it is declared to be (the genuine article). Material-based security protects against anti-counterfeiting and uses intrinsic properties of specific materials used to determine a product's authenticity. This can be additive (e.g. a label, tag or material added to the item or its packaging) or deterministic (e.g. recording unique properties inherent to the product itself).

The ISO Standard for Performance Criteria for Authentication Solutions used to combat counterfeiting of material goods [ISO12931:2012(E)] makes the distinction between overt and covert:

- **Overt authentication** can be directly performed by an informed inspector (refers to a role, and therefore could include a consumer authenticating a product) and does not require any additional equipment to allow a feature to be verified as genuine.
- **Covert authentication** elements are not instantly recognizable or interpretable by the human senses. They require authentication tools and/or specialized knowledge to verify their presence and validity.

4.2.1 LAYERING OF AUTHENTICATION / SECURITY FEATURES

There exist a number of technologies that allow industry operators, and consumers, to self-monitor the authenticity of products in the market, whilst providing authorities with robust tools for enforcement.

Currently, leading practice in the security industry (security documents, bank notes, tax labels, etc.) is "**security layering**". This entails combining multiple security features and dramatically increasing the challenge to potential counterfeiters and illicit traders.

The North American Security Printing Organisation (NASPO) recommends a basic security package that should comprise layering overt, covert (invisible) and forensic security features.⁴⁴ Forensic features are identified through laboratory analysis and provide proof of authenticity



Figure 21 - Basic security package should comprise overt, covert and forensic elements

⁴⁴ NASPO, 2009. How to Select a Security Feature: A structured Guide for the selection of a Security Technology for Documents and Items of Value.

that can be used for evidence submission in a court of law.

By combining a package of security features, access can be controlled for different inspectors (e.g. consumer, distribution chain operators, enforcement authorities) and also increase security so that no one party has access to all the elements.⁴⁵ It is for this reason that Covert is sometimes further divided to include “semi-covert”. Like covert, “semi-covert” requires a device, but this might be a much simpler device such as a UV torch, polarising filter or loupe which may make it suitable for distribution chain operators, whilst the covert feature, which is verified using a more sophisticated device, may be reserved for Government authorities.

In recent years, an additional layer comprising information security was also added, including encryption and online verification techniques to increase overall security.

Combining **Authentication and Traceability** provides a robust mechanism to combat counterfeiting, detect smuggled goods not authorised for an internal market, and guard against goods movement frauds (diversion, “ghost” exports, carousel fraud) within and between EU Member States. This is achieved because the traceability information based controls are tied to the physical good themselves.

4.2.2 MAPPING SECURITY FEATURES TO THE PROBLEM STATEMENT

The TPD refers to both “visible” and “invisible” security features – whilst security features are categorised by their method of authentication.

Based on the problem statement in section 2 above, it is understood that:

- “Visible” refers to an **overt** security feature. By visible, it is intended that consumers are able to use the feature to authenticate a tobacco product without the use of any additional tools or equipment – certainly an important consideration, given the size of this user group of well over 100 million smokers in the EU⁴⁶.
- “Invisible” refers to a **covert** security feature, suitable for use by EU and Member State authorities to validate products in the field. As this is a considerably smaller user group, equipment and training to authenticate the cover feature is a practical consideration.

This maps the security feature to the functional requirement of consumers and EU authorities in the field. However, as aligned to the NASPO recommendations and ISO12931:2012(E), a 2nd category of “invisible” also be considered to include a forensic security element as the 3rd layer.

RECOMMENDATION

- During development of enabling legislation and policy, the EU Commission may consider specifying the required categories of security features using terms aligned to the NASPO and ISO12931:2012(E). It is anticipated that this may aid keeping the EU Commission standards aligned to the intended objectives of the TPD.
- Member States may consider the addition of including a forensic security element for the purposes of collecting court-admissible evidence to support investigation and enforcement efforts by Member States.

⁴⁵ ISO 12931: 2012(E)

⁴⁶ http://ec.europa.eu/health/tobacco/policy/index_en.htm

4.2.3 OVERVIEW OF SECURITY FEATURE CATEGORIES

The security feature categories include:







Category	Description	Examples ⁴⁷
Overt	Security features that can be verified by naked eye, such as colour changing inks, holograms, latent images, watermarks and security threads. Almost always a visible security feature.	
Semi-Covert	Security features requiring a simple tool that does not require limited training such as UV Fluorescent inks and specialised print techniques (e.g. micro text), and a simple device (e.g. UV torch).	
Covert	Security features that can be authenticated by only using a dedicated and specialised electronic readers for authentication, such as proprietary taggants or special invisible inks.	
Forensic	Security features including forensic markers identified through laboratory analysis providing irrefutable evidence that could be submitted as evidence in a court of law.	
Physical Security / Tamper Evident	Security features, including techniques to provide tamper evidence and elements to prevent transfer and reuse.	
Emerging	Security features using material fingerprinting and entropy-based / chaometric authentication techniques. These can include visible elements which provide covert and semi-covert elements which require specialised techniques to authenticate.	

Table 14 - Summary of Security Feature Categories

The following section provides an overview of available security feature technologies within each of these categories. The purpose of this next section is to provide some overview and context of these technologies and their application, and is a distillation of several information sources including public references, industry reports and brochures⁴⁸.

⁴⁷ Example Image sources: <http://www.prooftag.net/>, <http://www.labellock.com/>, <http://banknotes.resbank.co.za/>, <http://www.eltronis.com/>

⁴⁸ Sources include research from multiple sources including IRACM (Insitute for Research Against Counterfeit Medicines), Reconaissance-International, SecuringIndustry.com and public sources.

4.2.3.1 OVERT SECURITY FEATURES

Overt security features are apparent, immediately visible and can be verified by the naked eye (or human senses) without any additional equipment or devices. These security features are most suited for consumers to authenticate a product as legitimate and ideally should **require no (or minimal) training** and the security feature should **provide a clear and unambiguous result**. The following table outlines the different types of overt security features:

Security Feature	Description
Barcode and Product Coding	A Barcode is a series of vertical printed bars of controlled thickness and separation representing variable data information in a linear format. A 2D barcode consists of a representation of solid and clear images (usually squares) in a matrix format over a specific two-dimensional structure. Barcodes and code verification services are sometimes marketed as an overt (or "digital") security feature, but in standard form offer no protection against reproduction, making this a relatively weak when used in isolation.
Colour Shifting/Changing Inks	Optically Variable Inks offer a visible colour-shifting effect, changing colour when viewed at different angles. Advantages are instant verification. They can easily be used on Tobacco packaging and are often found on banknotes. These inks are fairly secure but there are similar effects that can be created using substitute materials (i.e. nail varnishes and auto paints). Applying photonic colour offers enhanced optical effects beyond that of optically variable inks, including iridescent effects. Since they do not depend upon pigments or dyes, they deliver brighter colour.
Holograms	Holograms are optically variable images created through the interference of two laser beams. Holograms are the most common type of diffractive optically variable devices. There are two classifications of holograms, embossed holograms, which are holograms stamped onto metalized foil and reflective holograms that form an image by reflected light. It is possible to copy embossed holograms if they do not have additional features, such as concealed images, guilloche patterns, taggants, serial numbers, kinetic images, micro texts, etc. Embossed holograms are typically lower cost, but the use of reflective holograms may be considered somewhat more secure because the film needed to manufacture reflection holograms is more controlled with limited availability.
Hot and Cold Foil Stamping	Hot and Cold Foil Stamping involves the use of heavy embossing dies in combination with hot or cold applied foil. It is effective because foil is reflective and its metallic effects cannot be copied. Hot foil stamping also has properties that include high abrasion, scratch and temperature resistance. Holograms can also be used on the foils.
Other Optically Variable Devices (OVDs)	OVDs are visible features with dynamic characteristics that change according to the viewing angle, for example from one colour to another, or from one image to another. OVDs are similar to holograms but can include other devices such as image flips, or transitions, often including colour transformations or monochromatic contrasts.
Security Threads and Fibres	Security threads are polyester threads that are either fully or partially embedded down the length of the paper. Fully embedded threads can only be viewed when the document is held up to the light. Partially embedded threads appear intermittently on one side of the paper. Security fibres are small fibres randomly distributed throughout the paper while it is still in the pulp form. The fibres may be coloured or have fluorescent dyes only visible under UV light.

Security Feature	Description
Watermarks	A watermark is an image in paper produced by varying the thickness and density of the paper mass during paper production. These variations form a distinguishable image that can be viewed when holding the paper item up to the light.

4.2.3.2 SEMI-COVERT SECURITY FEATURES

These following security features require a simple tool and minimal training to authenticate the product:

Security Feature	Description
Latent Images	<p>Hidden Image Technology (HIT) embeds an image in the print on a product. These effects can be created for detection either by tilting the printed image in a particular manner, by means of using a simple validation device.</p> <p>A latent image detected by means of tilt is created by printing certain elements of the image with a special raised ink. Looking directly at the printed image, it is not apparent that some ink elements are slightly raised compared to others, but as the printed image is tilted and viewed at an angle, the raised ink becomes apparent, obscuring the non-raised printed elements to create a visual effect.</p> <p>A covert feature can be created by embedding visual artefacts in the image that can only be seen by a special optical lens (film overlays such as polarizing filters). This lens allows only specific areas of the image to be revealed at any one time. As the inspector moves the filter around and finds the correct alignment, the part of the image containing the hidden digitised image becomes visible. The hidden section scan shows different images as the lens rotates.</p>
Security Inks	<p>Thermochromic Inks: Inks that change colour when exposed to a change in temperature (hot or cold). It is used primarily on food and beverage products.</p> <p>Photochromic Inks: Inks that change colour when exposed to a UV light source. The inks can be coloured or colourless. The authenticity of a product/document with photochromic ink can also be checked by exposure to sunlight or other strong artificial lights. There can also be a hybrid of the Thermochromic and the Photochromic inks using cold and sun activation.</p> <p>Up-converting or Down-converting inks: These inks are colourless and transparent in normal lighting conditions but contain a fluorescent ink that emits light in the visible spectrum when exposed outside the human visible spectrum such as Ultra Violet (UV) or Infrared (IR) light. A device emitting light in the necessary spectrum to trigger this effect is required to check that this ink is in place. Laser Activated inks are similar to this, but only change colour when activated by a very specific frequency of light. For this reason, they are considered more secure than UV or IR inks, but require a more specialised detection device.</p> <p>Metameric Inks: Inks that appear differently according to the light source. For example, under normal light two items viewed under the same light appear identical, but when using a filter or other special illumination the colours on the items appear different.</p> <p>Coin Reactive/Scratch Off Inks: The image printed from these inks is white or transparent. The image is revealed when the edge of a coin is rubbed over the ink. This provides for immediate verification of authenticity without the use of any special devices.</p>

4.2.3.3 COVERT SECURITY FEATURES

The following security features can be authenticated only by using dedicated and specialised electronic readers for authentication:

Security Feature	Description
Digital Watermarks	Digital data embedded directly within video, audio or print content which is imperceptible to humans but readable by computers. The watermark may be embedded by means of subtle variations in colours, patterns or applied materials (such as varnish applied to printed material).
Forensic Markers/Nano-Taggants	Forensic Markers are molecular or microscopic particles that can be organic or inorganic in composition and exhibit specific and unique physical, biological, or chemical properties. They can be embedded into different aspects of the security features on a product, (e.g., holograms, security threads, etc.) Forensic markers are highly secure, but also high in cost and may be hard to control in multiple markets. All of the above inks can be further enhanced by the addition of covert forensic markers in nanotechnology formulation.
Radio Frequency Identification Device (RFID)	RFID's are small microchips containing, or able to contain, unique and individual information related to the item to which the chip is attached. The chip, and therefore the information, is addressed by means of radio waves which are conveyed to the chip by means of an attached antenna. These devices are now so small that they can be neatly implanted into plastic cards or paper. They can typically be detected at distances ranging from a few millimetres to several meters.
Security Inks	Magnetic Inks: These inks contain small iron oxide magnetic flakes and allow a number to be machine read. The inks have two filmic layers, one carrying an invisible (magnetic) image and the other an invisible magnetisable layer. Magnetic inks are mainly used for serialisation and numbering purposes but are also found in base security inks within banknotes.
	Conductive Inks: A conductive ink results in a printed object which conducts electricity. These inks allow circuits to be drawn or printed on a variety of substrate materials such as polyester to paper. This can result in optical effects, such as flashing 'lights' or to make covert messages visible.
	Biometric Inks: Biometric inks contain DNA taggants that can be machine read or react to a reading solvent. This allows for verification of a genuine product. These are completely covert but require specialist methods to validate the authenticity. There are optical machine-readable taggants that require a UV/IR light energy reader – if wavelength response matches calibration of reader then ink is authentic. There is also magnetic based taggants that is a physical based system, not chemistry based. A handheld device, similar to MRI, is used to authentic inks.

4.2.3.4 TAMPERPROOF AND TAMPER EVIDENT FEATURES

Tamper evident solutions are devices such as seals, closures, tapes, etc. that demonstrate whether the product or packaging has been opened or breached. Tamper resistant solutions provide a barrier to tampering by either normal users or others with physical access.

Tobacco companies typically use tear strips, while other industries use solutions, such as special closures that, in addition, intend to prevent refilling or reusing the container. The type of packaging container used can also intend to prevent reuse (pouches, tubes, aerosol cans, etc.).

For the purposes of this report, it is assumed tamper proof, as contemplated in Article 16 §1, relates to tamper resistant elements of the security feature. ISO12931: 2012(E) defines tamper resistance as “the ability of the authentication element to resist the removal, alteration or substitution of the element from the material good or its packaging.” Tamper resistance of only one of the elements the ISO standard identifies as a means for “attack resistance”. Other attack resistant elements include resistance against reverse engineering, copying, alteration, side channelling, interception of communication between the security feature and any authentication tool, obsolescence and uncontrolled reuse.

Examples of methods to add tamper resistance to a security package include:

- Mixing strong and weak elements into the combination of materials (substrates) and bond layers (such as the adhesive or method by which the security feature is affixed). For example, the security feature might be applied using pressure self-adhesive glue, which has greater bond strength than the paper substrate. Therefore, attempts to remove the security feature will cause the paper to separate thereby damaging the feature.
- Micro cuts / die cuts that create a weakness in the materials in the feature that are damaged during attempted removal. Alternatively, soluble or chemical sensitive materials may be included in the substrate that dissolve and stain the security feature should it come into contact with solvents or liquids that may be used during tampering attempts. An example may be including a chemical that reacts and changes colour in the presence of solvents that may be applied by attackers attempting to remove the security feature to reuse on fraudulent packs.

4.2.3.5 EMERGING TECHNOLOGIES

There is a growing segment of security features that use material fingerprinting and entropy-based / chaometric authentication techniques. These include semi-covert elements that require specialised techniques to authenticate. Surface area authentication involves taking a “fingerprint” of a small area of a product packaging at the nanoscopic level. This can be the natural occurring “fingerprint” or something can be added to make it unique and identifiable (random fibre orientation, or bubbles created in a substrate).

Once the fingerprint has been captured from the material, it is then stored. In several cases, an algorithm is used to analyse the fingerprinted information and generate a result that can be readily stored.

Then, when an item needs to be authenticated, this same area of the packaging is then “fingerprinted” again. Where an algorithm was used, this is then applied to generate a result, and this information is then compared to the original fingerprint to verify if it is indeed the same item. For practical reasons, the algorithm allows for some leeway to accommodate some wear or damage to the fingerprinted area, slight differences of the positioning of 2nd fingerprint, as well as slight manufacturing variations in the capture device itself.

While the security feature may have a visible component, it should be considered semi-covert because references to an online database, algorithm and a device is needed to verify that the “fingerprint” is authentic (e.g., smartphone with a lens adaptor to improve the capabilities of the camera).

These fingerprinting technologies offer an opportunity to authenticate a product with great certainty. However, at this stage, cost and speed (in particular the fingerprinting process) are the main barriers to the adoption of this technology.

It should be mentioned that a 2nd emerging technology for product authentication are the category of devices that use spectrographic techniques to verify the chemical composition of the product itself. In particular, this technology is being pioneered to combat the growing problem of counterfeit pharmaceuticals.



Figure 22 - Spectroscopy devices allow verification of chemical compounds (Source: www.ahurascientific.com)

Spectroscopy devices allow base pharmaceutical ingredients or finished products to be tested to verify presence of the correct chemical compounds or added taggants. This technology has made inroads to aid in the detection of counterfeit tuberculosis and counterfeit malaria medication in several developing economies. However, it is not anticipated as necessary for the EU tobacco control problem statement at this stage.

A further emerging technology relates to the increasing ubiquitous computing devices, including smart phones and wearables (such as smart watches), and its anticipated that these may increasingly offer workflows for / to support authentication. As an indication of the adoption cycles, penetration of smartphones in Western Europe reaching 49% at the end of 2012, with the prediction that this will have reached 78% in Western Europe and almost 50% in Central & Eastern Europe by 2017⁴⁹. Therefore, while indeed a technology area to monitor in the medium / long term, it is not anticipated that these will have reached sufficient prevalence / adoption to offer an authentication mechanism accessible to all consumers in the EU.

4.2.3.6 SECURITY FEATURES RELATED TO PRINTING TECHNIQUES

Several secure printing techniques have been invented and developed over recent centuries, primarily driven by the need to secure documents of value. Generally, these techniques take advantage of specific characteristics and capabilities of the very large, precise and expensive printing equipment operated by security printers and are therefore not generally available commercially or to the public.

Security Feature	Description
Intaglio Printing	The area of the image to be printed is recessed into the surface of the printing plate via engraving or etching and the recessed areas filled with ink. This area is filled with high viscosity inks, the excess is wiped from the plates and heavy pressure is applied to transfer the ink to the paper. The resulting raised ink profile gives intaglio-printed documents their characteristic tactility. Gravure is a type of intaglio printing.
Flexography	Flexography is the method of printing whereby a mirrored 3D relief of the required image is made in a rubber or polymer material. A measured amount of ink is deposited upon the surface of the printing plate, the print surface then rotates, making contact with the print material (substrate) and transferring the ink.

⁴⁹ Smartphone Penetration, Section 1.2, "Mobile Economy Europe 2013", GSMA Intelligence.

Security Feature	Description
Guilloche	Engraving technique that allows very complex, intricate and precise patterns (repetitive geometric shapes).
Microprinting	Printing that is so small that it cannot be reproduced by photocopying or scanning, and which can only be read under magnification.

4.2.4 AUTHENTICATION DEVICES

There are different authentication devices available, according to the level of authentication that needs to be provided, and to which user(s). Obviously, consumers will not verify authenticity at the same level as EU enforcement officers and therefore would not need to be equipped with the same tools. Consumers will need immediate and easy means to authenticate products and therefore will rely on *overt features* that can be authenticated with no devices (generally by the naked eye) – an important consideration where providing tools and training would not be practical in the context of well over 100 million smokers of tobacco products in the EU. Field enforcement inspectors would need more sophisticated tools to access more covert and sophisticated security features and information.

Table 15 - Summary of Authentication Devices available for different stakeholders

Targeted User	Feature	Description
Consumers	Eye	Overt security features can be verified by any user as a first level of authentication. It relies on physical material security which affects the feel or look of the product.
Consumers	Mobile Phone	More and more security features incorporate a security element that can be verified using mobile phones. They provide a means for users to get information in the field about the product and verify the origin.
Supply chain, enforcement	Filter, UV lamp, magnifier	Provided to supply chain stakeholders, as well as enforcement officials, to verify semi-covert security features.
Enforcement	Yes/No device	Usually provided to field inspectors, they provide immediate answer (Yes or No) on the presence or not of specific markers (covert feature) incorporated as part of the security feature.
Enforcement	Dedicated electronic device	Only provided to enforcement officials, they provide further security and are more reliable than mobile phone as they feature specific functionalities allowing further information for enhanced verification. These devices can take various forms, and can include PC accessories devices (e.g. readers, scanners or microscope cameras), add-on hardware for mobile commercial devices, or self-contained proprietary hand-held devices.
Support for Legal procedures	Laboratory equipment	Use of knowledge and dedicated scientific methods to validate the authentication elements or intrinsic properties of the material good. To be acceptable by a legal authority, forensic evidence may need to be established by a trusted third party ⁵⁰ .

⁵⁰ ISO/IEC 12931:2012—Performance criteria for authentication solutions used to combat counterfeiting of material goods, Categorisation of authentication elements, Forensic Analysis.

4.2.4.1 DIGITAL MASS SERIALISATION (DMS) AND DIGITAL MASS ENCRYPTION (DME)

Digital Mass Serialisation (DMS) involves the generation of a random or pseudo random code, or number, which is unique for each product. When a batch of codes is generated, they can be transferred to the manufacturer, who can print the code directly onto the packaging during the production process or print on a label that can be placed on the product packaging. The code is inserted into a database for verification by the customer or provider. Verification is confirmed by the presence of the code in the database.

The code is normally printed in human readable form in addition to its 2D barcode form. DMS technology providers can also incorporate their own SMS (short message service), which can be sent by the consumer using a mobile phone, and they can then wait for a verification message. This method has largely been surpassed by the use of barcode readers on mobile phones. The consumer simply takes a picture of the 2D barcode, which is then sent through wireless Internet technology to the code provider for authentication purposes. Successful DMS systems should automatically relay failed verification attempts to providers, containing information such as location, time and date.

The success of DMS technology is reliant on the implementation of thorough operational protocols. An advantage of DMS technology is the ability to offer consumers a mechanism to verify the serial number. The major disadvantage or threat to DMS technology is the security of the provider database. In addition, as databases become larger, the process of finding and authenticating individual products will inevitably require longer times. The solution to managing these potentially extremely large databases is adopting the use of high-end database software and technology, naturally incurring higher costs.

Digital Mass Encryption (DME) attempts to address these disadvantages by employing a cryptographic algorithm that generates the codes, and this eliminates the dependency on a database. DME only enables a code to be verified once it has been decrypted by both the algorithm and the key used for its creation. The codes produced are unique and unpredictable and usually they do not contain any dynamic information associated to the product (e.g. location or next destination).

DMS and DME approaches for authentication by themselves offer no protection against counterfeiters simply replicating codes "stolen" from valid packs, and then reproducing them on illicit goods. To detect this, DMS and DME rely on high levels of consumer verification to be effective, and for such cases of duplicated codes to be identified.

This approach may therefore be suitable for items where a significant portion of the population is subject to authentication. Such an example may be an approach for pharmaceuticals in the EU under the Falsified Medicines directive, where it can be mandated that the serial code of every pharmaceutical item is checked at the point of dispensation. However, in the case of tobacco control and the low inspection rates anticipated in this domain, DMS and DME are likely to **provide a largely ineffective authentication solution** allowing reproduced fraudulent codes to go relatively undetected. ISO16678: 2014(E), "Guidelines for interoperable objective identification and related authentication systems to deter counterfeiting and illicit trade" identifies the issue of unique identifiers being duplicated by illicit operators, and that an authentication element should be used to mitigate the risk of duplicated unique identifier codes. This might be intrinsic security layer options to the code itself (including security inks, taggants, optically variable devices and other authentication features, embedded security keys, encrypted information related to the secure element and physical uncountable functions or markings).

4.2.5 KEY CONSIDERATIONS FOR THE TOBACCO DOMAIN

Security features applied to products provide Government not only with a means to control the supply chain but to also protect consumers from products that are unsafe and harmful. Over and above combatting counterfeit goods – these features must combat illicit activities potentially undertaken by criminals.

Therefore, the security features should complement the traceability programme, and take into account Government controls required across the end-to-end track and trace process, as outlined below:

- **Authorising Security Feature Users:** Registration of manufacturers, manufacturing facilities and products (product identifier at level of stock keeping unit (SKU). Secure production of security feature materials (based on forecast production volumes).
- **Delivery of Security Features to Authorised Parties:** For security features that utilise a controlled additive, processes must be in place to ensure that only legitimate and authorised manufacturers are able to order and receive materials for application of the security features to products for which the manufacturer is registered.
- **Application and Quality Control:** Ensures that only legitimate manufacturers are able to apply the feature to products, whilst on-production controls that ensure that the security feature, have been applied to all products.
- **Distribution Chain Verification:** In order to combat illicit products potentially entering the supply chain, the security features must enable operators in the distribution chain to validate the authenticity of products. The security feature should enable this to be performed quickly and with high-degree of certainty. Importantly, this also provides the means for EU authorities to hold distributors accountable should they trade illicit products.
- **Market Surveillance and Enforcement:** Enforcement agencies play an important role in managing compliance levels of manufacturers and distributors, and ensure unmarked and illicit products do not enter the market. Because available enforcement resources are limited, the security feature should make field inspection as quick and efficient as possible, whether at the border, in the distribution chain or during inspections in the retail market.
- **Consumer Authentication:** The security feature must support a Consumer's ability to easily check the authenticity of the security feature and provide some assurance that the security feature is genuine. For consumers this should be overt, and therefore possible to check by the human eye, without requiring a device or equipment.

In selecting the appropriate security features, the technical aspects of the implementation also need to be considered. The security features need to be suitable for the products being marked, and the manufacturing environment itself:

- Suitability for application on very high production line speeds – some of the fastest manufactured consumer goods include beverage and tobacco industries with production lines running at over 2,000 products per minute;
- Application method needs to take account of manufacturing environment associated with the product – such as humidity, dust, and vibration;
- The ability for the security feature to provide an unambiguous and immediate authentication check result;
- Appropriate for the product being marked (in terms of providing a suitable cost/benefit).

4.3 CURRENT TRACK AND TRACE INDUSTRY TRENDS

4.3.1 BUSINESS DRIVERS FOR TRACK AND TRACE

The business drivers for track and trace can be categorized into three key areas: (1) Efficiency / Economic, (2) Security, and (3) Regulatory. Often, combinations of these drivers underpin the implementation of track and trace solutions. Most trace solutions that exist today are industry driven without direct mandates from regulatory bodies. However, this is changing. With the increasing prevalence of illicit trade now occurring in new categories (e.g., foodstuffs, Fast Moving Consumer Goods (FMCG), electronics, etc.) more regulations are emerging throughout the world.

There are a wide variety of track and trace technologies that are used in commercial supply chains, each with functional and cost-related implications. For commercial supply chains, the value of the goods is typically a key determinant in the amount of investment supply chain owners are willing to spend on technologies and systems for track and trace. High value goods (e.g., cell phones, medicines, etc.) are often tracked with theft prevention being the primary driver. Optimizing business benefits for all concerned stakeholders is the most optimal outcome when investments are made. An example of this would be systems that provide regulators with greater control, whilst delivering cost saving efficiencies to supply chain actors and ancillary benefits to end users.

4.3.1.1 EFFICIENCY/ECONOMIC

The operation of commercial supply chain includes the goods traveling via the supply chain from production to consumer, as well as the related assets and services along the chain such as conveyances (trucks, ships, planes) warehouses and any other waypoints. Track and trace technology is used extensively to better manage supply chains and reduce related costs. Large asset tracking and fleet management with respect to conveyances, for example, provides predictability and transparency and optimizes the utilization of the related assets. Container tracking is used extensively in fresh food supply chains to monitor temperature and other conditions as well as the functioning of the self-contained refrigerated containers used to transport the goods. A generator failure that goes undetected, allowing the goods to spoil is an avoidable outcome that supply chain owners are willing to spend money on to avoid. The figure below provides summary views of large asset tracking vs. FMCG from several perspectives for comparison.

ASSET MANAGEMENT		FMCG & FOOD	
APPLICATION	High value but low volume of items Examples: Reefer containers (cold chain), military, fleet management	APPLICATION	Still on-going / point to point Examples: Cold Chain, Meat and Fish
TECHNOLOGY	<ul style="list-style-type: none"> • GPS devices • Real-time GSM communication • Business Intelligence 	TECHNOLOGY	<ul style="list-style-type: none"> • Direct Marking • RFID • Tamper Band Seals • Freshness Indicators
BUSINESS DRIVERS	Efficiency & Security	BUSINESS DRIVERS	Supply Chain Efficiency
REGULATORY BASIS	Supply Chain Security (SCS)	REGULATORY BASIS	Industry driven initiatives
TRENDS	Escalating Operational Costs	TRENDS	Counterfeiting and Theft
VALUE OF ITEMS	\$\$\$\$\$\$\$\$	VALUE OF ITEMS	\$

Figure 23 – Large Asset Tracking vs. FMCG

Even though the supply chains are significantly different in terms of the other factors, the business driver of efficiency remains the same for both industry types.

4.3.1.2 SECURITY

Security concerns applies to a wide variety of supply chains and for different reasons and remains one of the primary drivers for such track and trace solutions regardless of the industry type. There are many military related instances where track and trace is used to ensure that sensitive munitions and materials do not end up in the wrong hands and other industries follow the same with the object of preventing illicit, counterfeit or potentially dangerous goods from entering into the market.

Track and trace solutions attempt to achieve these objectives by providing supply chain goods awareness (location, movement information, etc.) and goods integrity information (tampering, deviation, etc.). This assurance is invaluable to supply chain actors not only from a goods processing perspective but also from a business forecasting and control perspective.

4.3.1.3 REGULATORY

The final area for track and trace solutions is the regulatory driver. This alludes mainly to the regulations and stipulations placed on the private sector by public sectors such as governments and other regulatory bodies.

Government regulation is based on the need to collect revenues due, control and govern goods movement across and within their countries, as well as the need to protect consumers from potentially harmful goods. Regulatory bodies play a governance role over industries and are driven by the same motivators as governments but usually on a wider scale. Even though this driver is normally 'imposed' on the private sector by the public sector, the benefits realised as a result are on both sides of the supply chain.

4.3.2 EMERGING STANDARDS AND TRENDS IN TRACK AND TRACE

Computer networks make it possible to exchange information much faster than before, including the possibility to process data automatically. Geographical distances for data transmission are almost irrelevant. This enables organizations to set up inter-organizational operations faster than ever and with little or no human intervention, as long as different organizations implement the same protocols for data exchange (speaking the same language). Standards are the cornerstone for enabling such implementations where the effort does not depend on the number of organizations that exchange data. Beyond not being an obstacle for the challenge described in the Stakeholder Requirements Matrix, to be fit for the purpose and the domain, the selected standard(s) would ideally fulfil the following characteristics:

- Be compatible with existing logistics and manufacturing practices (in particular in the tobacco domain where high speed and reduced space are real constraints);
- Adapted to a global market (not only Europe);
- Support the distributed nature of the supply chain;
- Be neutral to avoid proprietary protocols and/or vendor lock-in;
- Maximize benefits for a given investment to enable/provide additional value for customers and brand;
- Have expertise widely available (to be able to be deployed at scale and on time, which is an important point for regulatory purposes) with guaranteed on-going support;
- Be flexible enough to evolve and embrace additional challenges along the way (new regulatory constrain, serialisation, encryption, extension for additional data/processes, etc.).

As mentioned earlier in the chapter *Definition and Components of a Track and Trace System*, the first part is item identification and, while it isn't rare to find domain-specific classifications systems, they are usually short-lived as the scope and domain becomes larger (e.g.: applied to a different domain, to another geography or for a different purpose than the one initially intended).

For example:

- International Council for Commonality in Blood Banking Automation (ICCBBA) manages, develops, and licenses ISBT 128 - an international information standard for the terminology, coding and labelling of medical products of human origin. ICCBBA manages the allocation of globally unique identifiers to licensed facilities and maintains the ISBT 128 Standard, international databases for Facility Identification Numbers and Product Description Codes, supporting documentation, and educational materials.
- The Health Industry Business Communications Council standard (HIBCC) was once predominant for Unique Device Identification (UDI) in the US healthcare industry, and while they are still accepted by the FDA, more and more large corporations are voluntarily transiting to the GTIN GS1 alternative, the reason being supporting double standards is not economically sound, especially when broader standards accepted in other parts of the world are available.

In another domain, *mpXML* is a standard initiated in 2001 by the meat and poultry industry as a response to the growing economic pressure for exchanging electronic information along the supply chain. After several years of evolution, it has embraced the concept of Data Key Element (DKE) and Critical Tracking Event (CTE), which was created by the Institute of Food Technologists (IFT) and since November 2013, is getting integrated into existing GS1 standards.

Additionally, in order to implement shipment tracking, it is necessary to identify shipments and products as individual instances (through a unique identifier) rather than just belonging to some product category. This also includes the unique identifiers that may be applied to containers, bundles, cartons and pallets containing multiple products, and used to track their movements. Company-specific tracking or serial numbers are currently the most used identifiers for product individuals. However, due to their company-specific nature, they are not suited for inter-organisational data exchange.

One example of a globally accepted and widely used shipment individual identifier is the serial shipping container code (SSCC) that is standardised by GS1. For data capture, the SSCC can easily be used with barcodes. However, the advances in radio frequency identification (RFID) technology, as well as the decreasing cost of implementing that technology, has opened up new possibilities for the identification of shipment and product individuals. RFID supports product individual-level identification nearly "by definition" since all RFID tags are associated to a unique tag identifier (TID), which is also the reason why RFID has paved the way to serialisation.

Even if several attempts have been made in the tobacco domain previously to use RFID, this technology is still seen as being too expensive to be deployed at item level.^{51 52 53} A hybrid approach (e.g. 2D Data matrix at item level and RFID at secondary and tertiary packaging level) is likely to be a better fit, but it also has the inconvenience of

⁵¹ RFID chips to curb cigarette smuggling - Tobacco Control Journal
- http://www.tobaccojournal.com/RFID_chips_to_curb_cigarette_smuggling.48648.0.html (accessed 03-04-2014)

⁵² RFID Halts Cigarette Smuggling For Brits
- <http://therfidiva.com/2011/05/13/rfid-halts-cigarette-smuggling-for-brits> (accessed 03-04-2014)

⁵³ Philip Morris Intl. Seeks to Make Serialized Bar Codes Work With EPC Network - RFID Journal. Available at: <http://www.rfidjournal.com/articles/view?3668/> (2007)

multiplying infrastructure costs (RFID portals and readers required for reading the 2nd packaging, with barcode readers required for reading the codes at item level). Therefore, RFID is likely to be confined for the time being to extremities of the supply chain, either for tracking returnable transport items (RTI) like crates used to handle raw tobacco leaves in China⁵⁴ or assist the inventory control of palletised tobacco products in a DHL distribution centre⁵⁵.

Some of the key differences between RFID and 2D barcodes are summarised in the table below.

Parameters	RFID	2D Barcode
Line of sight	No line of sight required	Line of sight required
Reading range	Few meters (passive) up to several hundred meters (active)	Few meters only
Orientation sensibility	None to moderate	Requires proper orientation
Simultaneous identification	Thousands tags per second (anti-collision dependent)	Read-only single item at a time
Security, counterfeiting	High security, hard/almost impossible to clone	Easy for copying/counterfeiting
Privacy	If not destroyed or deactivated, tag may be read remotely (e.g. after leaving a supermarket)	No private data available for remote reading
Rewrite, reusability	Support read and write capability	No write capability, static information
Tag lifetime	More than 10 years (passive), battery dependent (active)	Depends on carrier material
Resistance	Can be used in harsh environment	Weak, depends on carrier material
Functionality if damaged	Impossible	Possible
Interference with magnetic fields	Functionality is affected by magnetic fields	Not affected
Data storage	More data storage capacity (128 Kb for active tags)	Limited data storage capacity, dependent on print size and density (for example – typical size limit of 7Kb for QR code ⁵⁶)
Standardisation	Worldwide standards in place (used frequencies can be limited in some regions)	Worldwide standards in place
Size	Medium, small (25 mm ²), tiny (2 mm ²)	Medium, small
Cost	More expensive to produce the RFID tags	Cheaper to produce
Attachment	Currently requires two steps: tag creation and tag attachment	Single step: can be easily printed on product during manufacturing

Table 16 - Comparison of RFID and 2D barcodes

For the tobacco domain, existing practices are already indicating GS1 as a natural candidate as the use of Global Trade Identification Number (GTIN) is already a common

⁵⁴ The Reliability Research of the Good Receipting and being Put in Storage Process of X City's Tobacco Logistics Distribution Center - Jie Jin et al., 2013, Applied Mechanics and Materials, 444-445, 1665 (2013)

⁵⁵ Alfredo Molin, From EDC to eDC, Eindhoven, 17th of April 2012, p. 16 - www.irim.eur.nl/fileadmin/default/content/irim/research/centres/material_handling_forum/material_handling_events/komende_material_handling_seminar/presentaties/alfredo_molin.pdf (accessed 26-09-13)

⁵⁶ QR Code included as an indicative example, and is only one type of available 2D Barcodes

denominator for nearly all the manufacturers. The European Article Number (EAN) re-baptised International Product Number, Universal Product Code (UPC) and Japanese Article Number (JAN) can all be encoded as a GTIN. This global standard can be extended to respond to the serialisation challenge (i.e. having a global unique identifier). Of even more importance for the problem at hand, GS1 is a non-profit and neutral organisation that should encourage vendor *co-petition* in this relatively new space. Being user-driven, integrating good practices and innovation comes naturally as one of the challenge faced by the GS1 community.

It is important to notice that, while these standards are free to use, part of the business models⁵⁷ of GS1 is based on subscription fees to use the Global Company Prefix (GCP) that enable companies and organisations to assign globally unique identifiers to their products, assets, documents, locations, logistic units, returnable containers, etc.

On the next level (data sharing), successful examples of such standards in Supply Chain Management (SCM) are Electronic Data Interchange (EDI) and RosettaNet standards. Supply chains are becoming more geographically spread out and loosely coupled⁵⁸, which signifies that they need to be able to set up new supplier relationships at a higher pace than before. Concepts used for this kind of loosely coupled supply chains are *Virtual Enterprises*⁵⁹ and *Extended Enterprises*⁶⁰. Loose coupling is particularly challenging for inter-organisational data exchange, which still often requires long and expensive setup of EDI communication. Even after EDI integration, supply chains have great challenges in implementing fundamental operations such as tracking shipments and deliveries. The Advance Shipping Notice (ASN) in EDI is the message that gets the closest to shipment tracking but it is neither suitable nor intended for shipment tracking. This is why most shipment tracking systems are organisation-specific, such as those provided by companies like DHL, FedEx and the like. In the tobacco product supply chain; due to the multiplicity of actors involved, there is already a standard in place that allows for the correct orchestration of the goods movements, independently of their nature and/or manufacturers.

Several initiatives have been created for implementing inter-organisational data exchange protocols and interfaces, such as the DIALOG (Distributed Information Architectures for collaborative Logistics) initiative at Helsinki University of Technology⁶¹ and the peer-to-peer based paradigms of the company Trackway with its WWAI (World Wide Article Information) protocol^{62 63}, however the one that prevails today is the EPCIS that was initially developed at the Auto-ID Centre at MIT.

⁵⁷ The GS1 business model varies according to the entity or organisation member in charge of the implementation in every country.

⁵⁸ Holmström, J., Framling, K.: Design Patterns for loosely coupled trace, track, configuration, and check operations in multi-company environments. In: Proceedings of EUROMA Conference 2005, pp. 329–337 (2005)

⁵⁹ Kim, T.Y., Lee, S., Kim, K., Kim, C.H.: A modelling framework for agile and interoperable virtual enterprises. *Computers in Industry* 57, 204–217 (2006)

⁶⁰ Estrem, W.A.: An evaluation framework for deploying Web Services in the next generation manufacturing enterprise. *Robotics and Computer-Integrated Manufacturing* 19, 509–519 (2003)

⁶¹ Karkkainen, M., Ala-Risku, T., Framling, K.: The product centric approach: a solution to supply network information management problems? *Computers in Industry* 52, 147–159 (2003)

⁶² Framling, K., Harrison, M., Brusey, J., Petrow, J.: Requirements on Unique Identifiers for Managing Product Lifecycle Information - Comparison of Alternative Approaches. *Int. J. of Computer Integrated Manufacturing* 20, 715–726 (2007)

⁶³ Juan Pedro Muñoz-Gea, Pilar Manzanares-Lopez and Josemaria Malgosa-Sanahuja. Advantages and New Applications of DHT-Based Discovery Services in EPCglobal Network, *Designing and Deploying RFID Applications*, Dr. Cristina Turcu (Ed.), ISBN: 978-953-307-265-4, InTech (2011)

4.3.3 EPCIS AS LINGUA FRANCA FOR SUPPLY CHAIN VISIBILITY

In 2007, EPCglobal (now a part of GS1) released its first standard for the Electronic Product Code Information Services (EPCIS), with the goal of making RFID data widely available, understandable, and actionable across supply chains.

In some respects, the EPCIS concept has not gained the traction initially assumed, as the collapse of the original Wal-Mart RFID program failed to match the initial expectations, but there are signs EPCIS is becoming relevant again, interestingly, more so globally than in the US, with particular interest in food safety and pharmaceuticals applications.

Though the concept dates back a decade ago from the Auto-ID lab at the Massachusetts Institute of Technology (MIT), today EPCIS is a standard from GS1 that defines interfaces enabling logistics events to be captured and queried as they occur in the supply chain and is not exclusive to RFID. The query interface, implemented using XML-based Web-Services, enables business applications to consume and share data within a given company or across companies in a supply chain network and became largely supported by large IT companies like IBM, SAP, Axway, or Samsung.⁶⁴

STANDARDS AT THE CORE OF TRACK-AND-TRACE		
	EXAMPLE	STANDARD
EPCIS	WHO Ship-From, Ship-To, Buyer, Seller	GLN
	WHAT Products, Logistics Units, Assets, Relationships	GTIN, SSCC, GRAI, GIAI, GSRN
	WHERE Postal Locations, Warehouses, Floors, Rooms	GLN
	WHEN Time and Date	
	WHY Commissioning, Packing, Shipping, Receiving, Dispensing	Business Step

Figure 24 - GS1 Standards at the core of Track and Trace

EPCIS provides a standard for enabling the "**Who, What, Where, When, and Why** of events occurring in any supply chain" to be exchanged, safely and securely. That includes information such as the time, location, disposition and business step of each event that occurs during the life of an item in the supply chain. Without such a standard, every company would likely define their own data models and "semantics" differently for logistics events as products move throughout the supply chain. Although the EPCIS uses the Electronic Product Code (EPC) as identification schema, it does not apply any restrictions and can work with any ID schema, e.g. EAN-13 or 2D codes. Extensions of the event format are possible, e.g., new data fields in the event message or new event types enable the adaptation of EPCIS to a particular domain.

⁶⁴ Basta, N.: "Information Technology Serialization Efforts Energize Track-and-Trace Technology", Pharmaceutical Commerce (2010), <http://www.pharmaceuticalcommerce.com> (Accessed 30-04-2014)

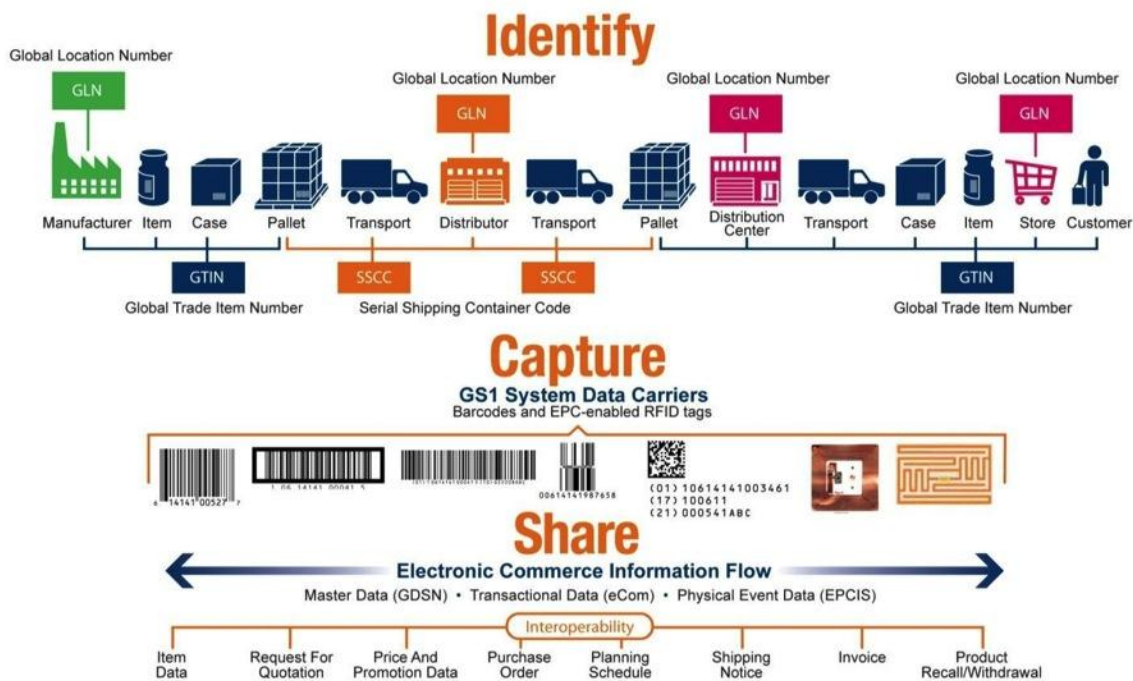


Figure 25 – The GS1 visibility framework

<pre> <ObjectEvent> <eventTime>2007-11-06T15:00:02.449Z</eventTime> <eventTimeZoneOffset>-05:00</eventTimeZoneOffset> <epcList> <epc>urn:epc:id:sgtin:0614141.000001.2</epc> </epcList> <action>OBSERVE</action> <bizStep>urn:epcglobal:cbv:bizstep:shipping</bizStep> <readPoint> <id>urn:epc:id:sgln:0614141.00300.0</id> </readPoint> <bizLocation> <id>urn:epc:id:sgln:061414100300.0</id> </bizLocation> </ObjectEvent> </pre>	<p>When </p> <p>What </p> <p>Why </p> <p>Where </p>
---	---

Table 17 - A typical EPCIS event in its XML format

The EPCIS data model was built with extensions in mind the outset. As a result, almost every part of the data model can be added to, and the allowed mechanisms are well defined and documented (e.g. to enable capture of transporter details, EMCS SEED number, etc.).

CATEGORIES OF EPCIS DATA AND RELATIONSHIPS

There are many categories of EPC related data. Some of these are attribute data, such as the manufacturing facility or its date of production. Other relations are dynamically built up over time, such as the history of where an object has been observed within a factory, distribution centre or retail store. Of the attribute data, some are defined at product-class level, while others are defined at instance level (i.e. may be different for each instance of a product class, e.g. date of production, expiry date). For the historical data (which means the data has a timestamp), it is important to be able to determine both

current status of an object (e.g. its last known location, this is the “tracking” part), as well as its history (trace of locations visited, the “tracing”). Also important is the ability to query the data using keys other than the EPC of the object: for example, in a product recall scenario, finding out the identities of all objects which passed through a particular contaminated location within a particular time range, however additional components are required to achieve this.

GS1 Key	GS1 Identification Key Title	Supply Chain Information Type
GTIN	Global Trade Item Number	Trade Item Class
GLN	Global Location Number	Locations & Trading Partners
SSCC	Serial Shipping Container Code	Logistics Units
GIAI	Global Individual Asset Identifier	Individual Assets
GRAI	Global Returnable Asset Identifier	Returnable Assets
GSIN	Global Shipment ID Number	Shipments
GINC	Global Identification Number for Consignment	Consignments
GSRN	Global Service Relation Number	Services Relationships

Table 18 – Type of GS1 Identification Keys

OBJECT NAMING SERVICE AND EPC DISCOVERY SERVICE

The inter-organizational nature of the business created the necessity to share and diffuse, in a controlled manner, the EPCIS data available in a particular depository or data store. For this purpose, the ONS (Object Name Service) is in charge of locating the authoritative metadata of a particular item and leverages the Internet to do so. Using part of the GTIN number as an index, it looks up for more information related to the product (The mechanism is similar to the one that transform a web address from a website into an Internet Protocol (IP) address. Another comparison would be to a geographic atlas as the information contained is relatively static compared to the Discovery Service). A master ONS (called root ONS), certified by an independent organisation such as VeriSign Inc., would serve as a single source of truth, but more detailed information is available at a local ONS, which serves as a cache for the sake of speed and for other practical reasons.

The Discovery Service (EPCDS) are used in complement to allow trading partners to search and discover who owns data associated with a particular EPC (the ONS is not supporting detailed information, like serialisation for example). A good analogy is to compare the EPCDS to a phone directory as it possess a more dynamic nature (it used to be called dynamic ONS), since the information for a particular product can be distributed among several partners along the supply chain and can require to be consolidated before having a complete view of the history of a particular EPC.

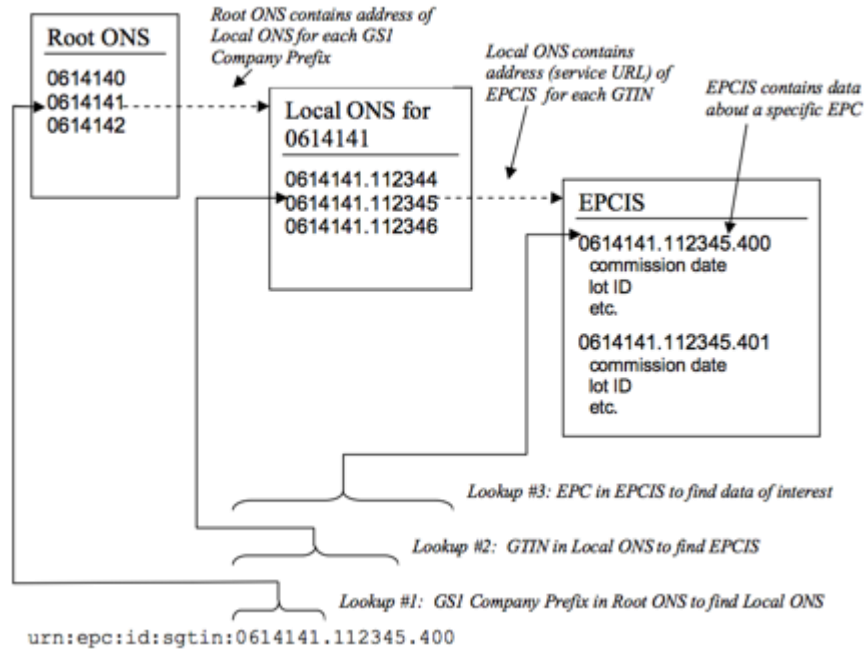


Figure 26 – Example of multi-step lookup through Root ONS, ONS and EPCIS

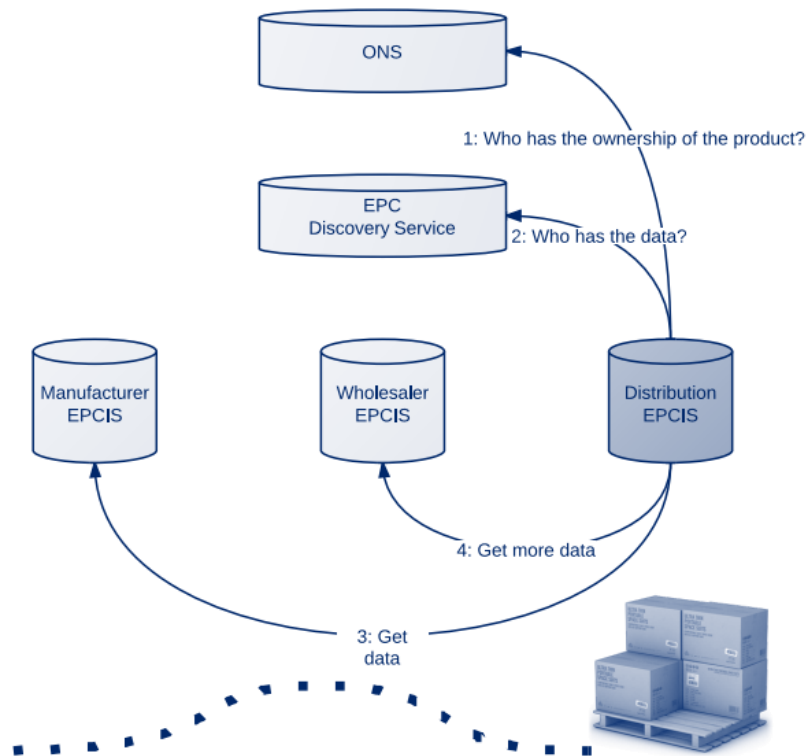


Figure 27 - Traceability information system using EPCIS and EPCDS⁶⁵

⁶⁵ Pardal, Miguel L., et al. "Enforcing RFID data visibility restrictions using XACML security policies." *RFID-Technologies and Applications (RFID-TA), 2012 IEEE International Conference on.* IEEE, 2012.

There are more than a handful of possibilities in term of architecture (Query Relay Model, ADS and SecDS to name few), each one has its own advantages and disadvantages that will impact on complexity, cost, data ownership and availability.⁶⁶ This analysis will be conducted later in this study.

The degree of oversight on a supply chain properly setup with an EPCIS framework is adjustable and depends on permissions. Theoretically, it can provided significant value for reporting for stakeholders such as:

<ul style="list-style-type: none"> ▪ Where is physical object x located at? ▪ Which physical objects are at location x? ▪ Where was the physical object x located at time t1? ▪ Where was the physical object x located during the time interval t1-t2? ▪ Which physical objects were located at location x at time t1? ▪ Which physical objects were located at location x during the time interval t1-t2? 	<ul style="list-style-type: none"> ▪ Detection of unusual patterns ▪ Risk analysis ▪ Rules based analysis ▪ Velocity consistency ▪ Dwell-time consistency (the time a product stays in a particular place) ▪ Lifecycle consistency ▪ Pair-wise shipping/receiving confirmation transition probability consistency
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The second column is considered somehow advanced analytics (e.g.: applied for fraud detection purposes) and does not necessarily apply here. It usually requires additional tools to be performed and depend on implementation. The size of the depository to analyse can also be a limiting factor.

⁶⁶ Advances in Internet of Things, 2012, 2, 37-46 <http://dx.doi.org/10.4236/ait.2012.22005> Published Online April 2012 (<http://www.SciRP.org/journal/ait>)

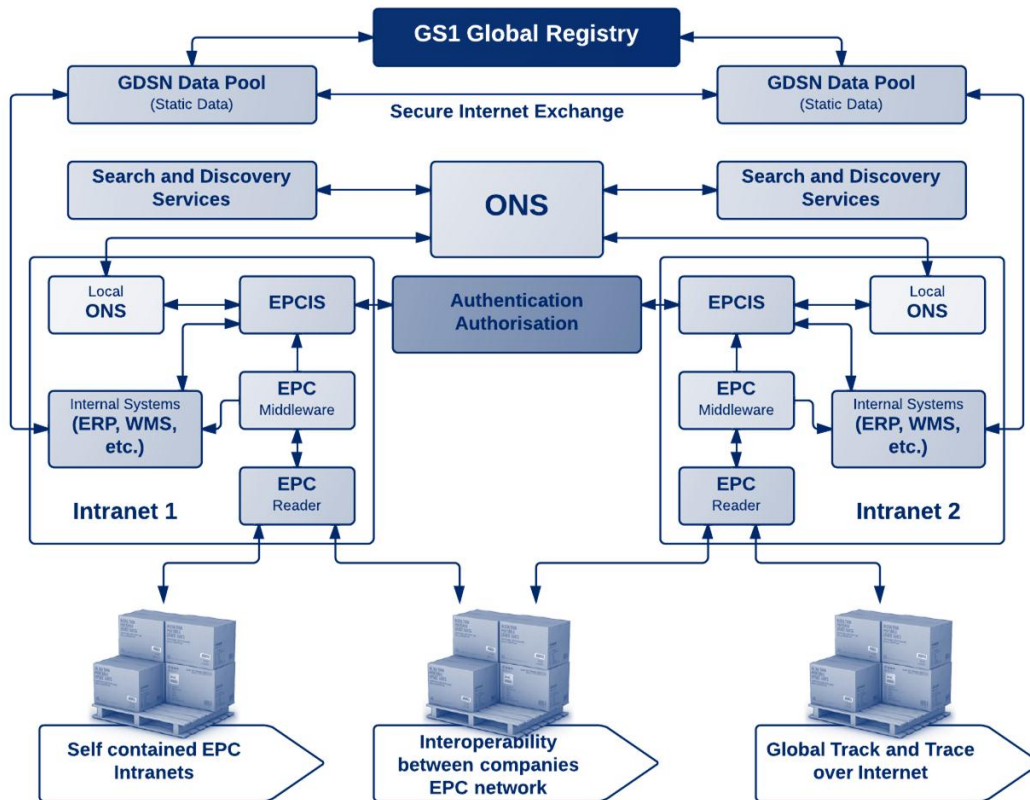


Figure 28 – GS1 Network Architecture & Components

CONCLUSION

By defining a shared minimum requirement and showing what action is required from trading partners, the GS1 traceability standard enables maximum interoperability between traceability systems across the supply chain whilst accommodating specific commercial, industry sector or legislative requirements. It serves as a foundation for identifying the unique requirements of each actor in the supply chain, and the service provider and/or integrators can add their own extension or leave out some of the components according to their needs or specific intent. The EPCIS standard is only a part of the GS1 ecosystem which itself has to communicate with other systems such as Manufacturing Execution System (MES) and Enterprise Resource Planning (ERP).

The EPCIS standard is designed as a platform with a uniform query and update interface to applications, while the actual implementation details and data binding to existing databases and information systems is not specified by EPCIS, which should therefore support simultaneous binding to multiple databases and information systems from multiple vendors. This implementation is a differentiating factor and usually reflects the maturity of the solution for the targeted sector, with every vendor flavouring his own EPCIS implementation to win the edge on the competition and/or solve a particular problem.

In sum, the GS1 standard offers a framework to establish a holistic view of the supply chain and create a bridge between the physical and the information flow. Its neutrality and general acceptance makes it well positioned to appropriately respond to traceability system design and implementation requirements. Specifically in the area of exchange and recording of traceability event data, implementation of EPC Information Service (EPCIS) may not be as high as levels of the other GS1 standards, though detailed EPCIS specifications have already been developed by GS1, with large-scale and mature applications just beginning to be exploited at large scale. EPCIS has been implemented

and supported by several software providers including the likes of IBM, Microsoft, Oracle, SAP, NEC, LG, as well as Fosstrak, an open source software project.

4.4 DATABASE MANAGEMENT KEY IMPLICATIONS

4.4.1 REQUIREMENTS FOR DATA MANAGEMENT

The selection of the proper architecture and underlying technologies must take into account the nature of the problem at hand. A review of the requirements inherent to a Tobacco traceability solution indicates a number of data management characteristics that should be addressed, considered in Table 19 below. The following sections review each of these key data management characteristics further.

Requirements of Traceability in the Tobacco Domain		Data Management Characteristics
Very large volumes of manufactured products that need to be tracked	→	High Cardinality
EU enforcement agencies using traceability data in the field require immediate feedback to support decision making	→	High Availability
Tobacco traceability within the EU community is being generated and accessed vast number of actors in the distribution chain, across multiple geographies	→	Distributed by Nature
Need for a central and consolidated view of tobacco traceability data	→	Sustained Data Ingress
Tobacco traceability data is commercially sensitive and may be a possible target for illicit operators	→	Security
Manufacturers are operating their production control systems that contain data required by the tobacco traceability solution	→	Master Data Management (MDM) Interface & Serial Generation
Need to cope with both legitimate day-to-day business exceptions and events, as well as mitigate risks of fraud	→	Monitoring, Inconsistency Detection & Reconciliation

Table 19 - Key Data Management Characteristics to be addressed for a Tobacco Traceability Solution

4.4.1.1 HIGH CARDINALITY

The primary single factor that differentiates the implementation of a track and trace system in the Tobacco industry is cardinality, which is probably second to any other track and trace system after the postal domain. The amount of tobacco items manufactured in Europe is estimated at 30 billion packs in 2010 and 90% of the market's share is distributed between the four major manufacturers.⁶⁷ Interestingly, to address the data volume problem in the pharmaceutical supply chain, Auto-ID Labs researchers introduced the idea of a Checking Services that could be run by trusted accredited third party service providers, enabling companies to outsource the burden of checking data, but this at the moment, specific to the pharmaceutical sector.⁶⁸

Relational database management system (RDBMS) are established candidates to store and query large amount of data and traceability is no exception. The large majority of these databases are based on the Syntax Query Language (SQL) which is largely

⁶⁷ Matrix Insight Ltd. - http://ec.europa.eu/health/tobacco/docs/tobacco_matrix_report_eu_market_en.pdf, 60.

⁶⁸ Auto-ID Labs Activity - Annual Report 2012-2013 (July 2013), p. 18-20 - <http://www.gs1.no/sfiles/7/07/76/5/file/auto-id-labs-annual-report-2013v13-final.pdf> (accessed in 04-05-14)

documented, available and understood by the IT community and is still today the most widely used database language since its inception around the 70's. Despite the fact that it became an ISO standard in 1987⁶⁹, small variations between vendor's implementations kept it from being completely portable, at the benefit of some major players.

Some suppliers are starting to consider alternative data storage and technologies to overcome some of the challenges presented by the growing amount of data that item-level serialisation represents, especially in scenarios where the data captured along the supply chain is inflating the data by an order of magnitude.

NoSQL technology as a viable option to tame the cardinality problem

CONSIDERATIONS

On the other side of the scale, the advent of social networks, search engines and genomics research have pushed the boundaries into the big data domain and billion events per day are not unheard of in organisations like LinkedIn⁷⁰, Twitter or Facebook⁷¹. Most of the technology used is available under open-source licenses and the opportunity to leverage of some of these technologies in the track and trace domain is real and must not be neglected. This will help to maintain the overall cost of the solution under control both in initial investment and on-going operation.

A potential limiting factor, at least currently, is the relative shortage in qualified staff to setup and maintain this kind of infrastructure, but the converging market of big data, Internet of Things and real-time analytics are putting the pressure on the market to fulfil the demand. Behemoths like Oracle, Microsoft, SAP and the like were, until recently, seen as the only viable alternative to store large amount of data, and have started to acknowledge this movement recently integrating the NoSQL offer in their portfolio to keep their market share.

Established research institutions are actively working to demonstrate the validity of the concept applied to supply chain visibility.⁷² An initiative sponsored by Samsung has for objective to develop a cloud based traceability network for groceries based on NoSQL technology.⁷³ ⁷⁴ Another push toward more acceptances into government's systems adverts from the announcement last October 2013 from the British National Health Services to migrate their infrastructure away from Oracle onto an open-source NoSQL distributed data store replacing a £1 billion program.⁷⁵ ⁷⁶

4.4.1.2 HIGH-AVAILABILITY

Despite being a regulatory tool, the implementation of the track and trace system envisaged must be the least intrusive possible and respect the business-driven nature of the industry: production interference or down-time should be avoided as much as possible. The same goes for the other side of the coin where the conditions to access the

⁶⁹ ISO/IEC 9075 (1-14) -- Information technology -- Database languages -- SQL

⁷⁰ Jay Kreps, 'The Log: What every software engineer should know about real-time data's unifying abstraction | LinkedIn Engineering', 2008. [Online]. Available: <http://engineering.linkedin.com/distributed-systems/log-what-every-software-engineer-should-know-about-real-time-datas-unifying>. [Accessed: 03- May- 2014].

⁷¹ Tuan Le, Seong Hoon Kim, Minh Nguyen, Daeyoung Kim, Seung Young Shin, Kyung Eun Lee, Rodrigo Righi, "EPC Information Services with No-SQL datastore for the Internet of Things," IEEE RFID 2014, Orlando, Apr. 2014

⁷² IoT-A EU-funded research

⁷³ KAIST The Three Musketeers, IoT, Cloud, and Big Data: One for All, and All for One.

⁷⁴ OLIOT (Open Language for Internet of Things) Open Source Project - <http://www.slideshare.net/gatordkim/oliot-samsungdaeyoungkimkaist-wideversionfinal> (accessed 18-09-2014)

⁷⁵ NHS tears out its Oracle Spine in favour of open source - <http://www.ehi.co.uk/news/primary-care/8949/spine2-built-on-riak-database> (accessed 24-03-2013).

⁷⁶ NHS 'to benefit from agile development' with selection of open source database Riak for Spine2 - <http://www.computing.co.uk/ctg/news/2300222/nhs-to-benefit-from-agile-development-with-selection-of-open-source-database-riak-for-spine2> (accessed 26-04-2014).

data for regulatory purposes must be guaranteed, low latency included. This can be troublesome since the design pattern for data storage is normally not favouring access to infrequently requested data. Also when failure happens, the system must continue to operate.

This is usually done through the implementation of fail-over mechanisms and redundancy of the critical components to avoid a single point of failure (SPOF) at all level of the system. If some point may tolerate degraded quality of service or even temporary failure, this should be clearly identified and the consequences carefully evaluated. In no way it should allow breaking the chain-of-custody of the data and putting the integrity of the system at risk.

4.4.1.3 DISTRIBUTED BY NATURE

As for any FMCG product, the tobacco supply chain is large and distributed both geographically and between entities (manufacturer, wholesaler, distribution and retail). It means that information is not living on a single instance of a database and must be shared between instances by passing messages through a network, which, under normal circumstances, is faster than the speed at which the goods are travelling (if not, inconsistencies occurs, something must be done, see *Monitoring, Inconsistency Detection & Reconciliation*).



Figure 29 - Cigarette Citadels: The Map Project⁷⁷

4.4.1.4 SUSTAINED DATA INGRESS

A direct consequence of the volume of data is the sustained speed at which the system must store the data, and while not particularly challenging at line or factory level, when taken at member-state or eventually at EU level, it can turn into a bottleneck. The data store, as well as the network, must be dimensioned properly to take this point into account to ensure a trouble-free operation, and thus at minimal cost. Buffering, Messaging Queue or Enterprise Service Bus (ESB) can help to cope with temporary loss of connectivity, reduced availability of a critical component and data-exchange between internal and external systems.

⁷⁷ <http://www.stanford.edu/group/tobaccopriv/cgi-bin/map> (accessed in 28-04-2014).

4.4.1.5 SECURITY

The whole point of having a track and trace system in place is protecting customers as well as legitimate businesses and the revenues they are generating. This cannot happen if critical data circulating in the system (serial numbers, aggregation information, origin, etc.) is vulnerable and attempting securing data that has been compromised is of little value. Data security is commonly subdivided into the following 4 attributes:

- **Confidentiality** – is the property that ensures that information is not made available or disclosed to unauthorized individuals, entities, or processes.
- **Integrity** – is the property that data has not been changed, destroyed, or lost in an unauthorized or accidental manner during transport or storage.
- **Availability** – is the property of a system or a system resource being accessible and usable upon demand by an authorized system entity.
- **Accountability** – is the property of a system (including all of its system resources) that ensures that the actions of a system entity may be traced uniquely to that entity, which can be held responsible for its actions.

Data security techniques like encryption, authentication, digital signatures, and non-repudiation services must be applied to data to provide or augment the system attributes described above. Further, security may be required to combat malicious services (where illicit operators may attempt to trick inspectors and users and route them to a malicious service that provides false traceability information). ISO16678: 2014(E), "Guidelines for interoperable objective identification and related authentication systems to deter counterfeiting and illicit trade" includes guidelines to mitigate the risk of this including using encrypted communication channels, digital certificate, periodic check that root of trusts is still valid, white lists and use of trusted websites as the entry point for verification services.

Since the whole system is as strong as the weakest of its component, additional control must be applied at other relevant levels (Physical and environmental security, access control, network and communication etc. This is addressed with the standard ISO27001:2013(E) – Information Security Management).

4.4.1.6 MASTER DATA MANAGEMENT INTERFACE & SERIAL GENERATION

Also derived from the asynchronous and distributed nature of the supply chain, there is the need for a Master Data Management (MDM) system which will insure, for example, that several manufacturing facilities that are attributing the same code to designate the same product, which is a necessity when a product can be manufactured in several sites or that a code indicating a location is not used twice for different places.

This important requirement is also linked to the accountability discussed in the previous paragraph, as a single view of the master data must exist between the different actors of the supply chain, for which the oversight of an external entity is normally required. The relevant characteristics of a product (brand, class, SKU, etc.) are often taken from the Enterprise Resource Planning system (ERP) into the MDM (when it isn't already a module of the ERP itself). The Manufacturing Execution System (MES) is usually tightly coupled through the production line interface with the serial generation and authorisation engine. The declaration of a new product or new production line goes through this interface at factory and a control of these operations is required to be able to identify the products being produced on a particular line (manufacturing line aren't always producing the same SKU and the overhead on production line operators to record such information should ideally be minimum in order to have a reduced impact on the yield of the whole production process).

A fundamental property of the MDM is transactional consistency as explained later in the section 4.4.2 below, so it is a natural candidate for traditional RDBMS. Also, the properties handled by the MDM are relatively static: the frequency at which they change is slow; as such there is no need for real-time data propagation and substantial latency (e.g. several hours) is perfectly acceptable.

In summary, this master data is the additional data that provides the necessary context for interpreting the elements of the event data (such as interpreting the identifier of a specific production line, and being able to reference the physical address of the facility). In contrast, the event data arises in the course of carrying out business processes, and grows in quantity as the items are progressing along the supply-chain.

4.4.1.7 MONITORING, INCONSISTENCY DETECTION & RECONCILIATION

Often overlooked, this is a fundamental aspect of a traceability implementation. A carefully designed rule-driven system preferably with government oversight (routing of incorrect data above a certain threshold, alert and escalation, etc.) is recommended to maintain a high standard of quality data and promote the adherence to good serialisation practices. Having reliable data transiting from one source (manufacturer, distributor) to the next (wholesaler, distributor) is essential since the information from a pallet is used to infer the content (i.e. every mastercases and packs contained within).

ALL THAT CAN GO WRONG – AND NEED FOR OVERSIGHT?

Example of possible inconsistencies (from www.gs1us.org/RxGuideline):

- | | |
|--|---|
| <ul style="list-style-type: none"> ▪ Overage Shortage ▪ Serial number Discrepancy ▪ Lot number Discrepancy ▪ Serial number And Lot number Incorrect ▪ Product Inference Problem ▪ Quantity Inference Problem ▪ Physical Inventory Overage ▪ Physical Inventory Overage (Concealed Overage) ▪ Physical Inventory Shortage (Concealed Shortage) ▪ Incorrect Customer/ Location Information ▪ Contains Incorrect Product Information ▪ Contains Incorrect Reference# Information ▪ EPCIS Ship Event Not Received ▪ Undelivered Shipment ▪ Lost Shipment ▪ Received Physical Product From An | <ul style="list-style-type: none"> ▪ Unidentified Sender ▪ Missing ▪ Could Not Read Data Due To Security Mismatch ▪ Data Not In Correct Format ▪ Good Product - Damaged Barcode Or RFID ▪ Damaged Product - Good Barcode Or RFID ▪ Damaged Product - Damaged Barcode Or RFID ▪ Damaged Shipment ▪ Resolved & Have Been Accounted For In Other Exceptions ▪ No Parent/Child Aggregation ▪ Data Incomplete ▪ Inconsistency / mismatch in traceability event chain ▪ Shipped Product To Wrong Customer & Data To Correct Customer ▪ Customer Refuses Order ▪ Unauthorised Return ▪ Shipment For Wholesaler Y Arrives At Wholesaler X |
|--|---|

Table 20 - Example of Possible Data Inconsistencies Requiring Monitoring

As a note and on the positive side of the balance, the type of data storage required for a traceability system have several characteristics that can be taken advantage of, such as the immutability. The data, once written to its final destination is unlikely to change. Even when travelling through the supply chain, the event-driven nature of the EPCIS standard will have the dataset appended with new event without modifying the previous one, like a ledger. This characteristic is interesting since it puts fewer burdens on the indexing mechanism that allows it to retrieve particular information on an EPC later on.

4.4.2 FUNDAMENTAL CONSTRAINTS INHERENT TO THE DATA ARCHITECTURE

A widely accepted theorem in networked shared-data system says that 2 out of the 3 following properties: Consistency, Availability and Partition Tolerance have to be privileged.⁷⁸ Without entering into further details, and for the sake of simplicity, it often results in choosing between Availability and Consistency (in reality leaving out Partition Tolerance in a distributed system is not a viable option for the majority of the cases).

- **Consistency** – means that once an update operation is finished, everyone can read that latest version of the data from the database. A system for which all the readers cannot view the new data right away does not have strong consistency and is normally called eventual-consistent.
- **Availability** – This is achieved if the system always provides continuous operation, normally achieved by deploying the database as a cluster of nodes, using replication or partitioning data across multiple nodes so if one node crashes, the other nodes can still continue to work.

As system scale is getting larger, it is difficult to leave out the Partition Tolerance. In the end, the goal is to end with the best combination of consistency and availability to optimise a specific application/scenario.⁷⁹

These basic notions are important to understand and assess correctly the consequences on the architecture, and the functionalities that need to be supported by the system.

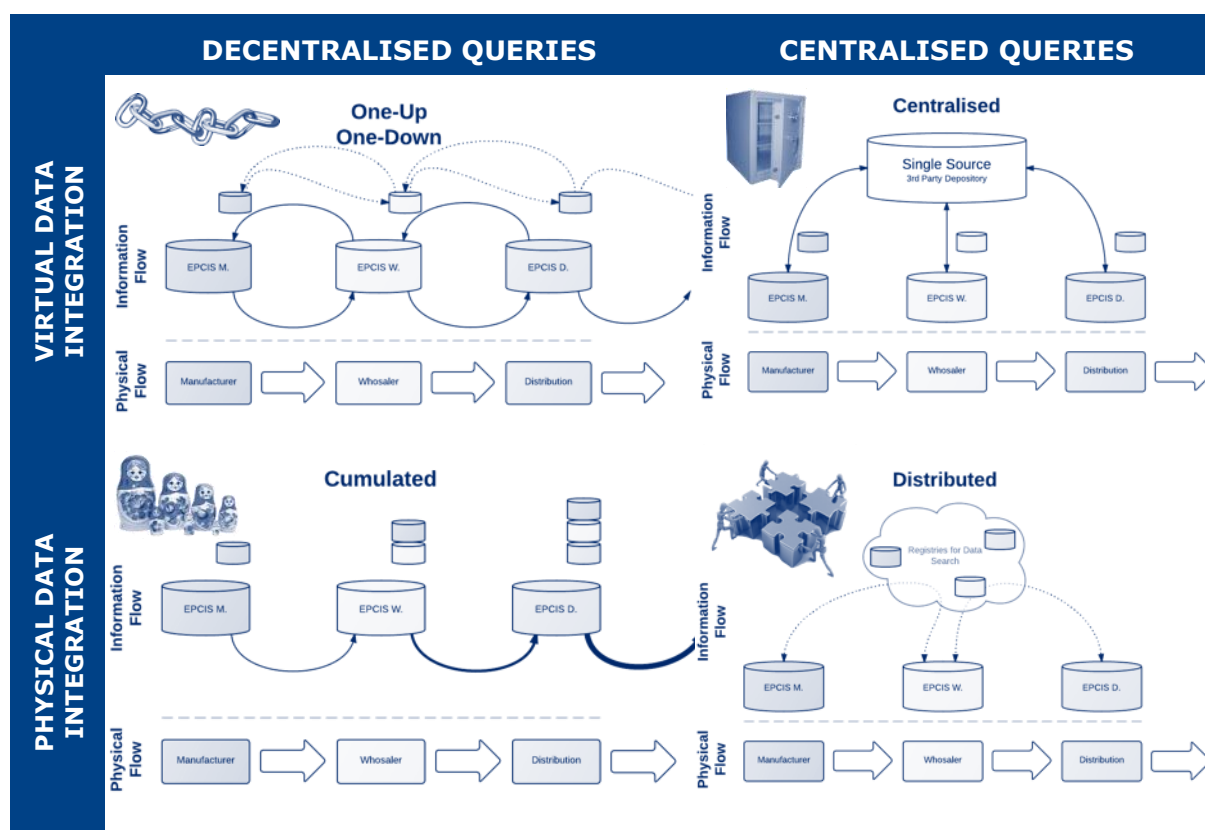
As many companies have experienced first-hand, running large databases poses a significant number of challenges, whose worst consequence is data loss or corruption (as long as an error doesn't lose or corrupt sane data, everything that went wrong can be fixed). This is further compounded by other factors, such as the product and regulatory requirements to retain the data for long periods. Managing these huge numbers is a significant burden on data management and selecting the proper architecture and technology is, as expected, a matter of compromises and priorities.

4.4.3 AVAILABLE MODELS FOR A TRACEABILITY SOLUTION

Whatever the chosen architecture, a local repository is required near the production line or at least, at the factory level. This is a by-product of the proximity required to mark the product during the manufacturing process, it also serves well the connection required to the MDM at factory level. Further, it reduces the impact of a loss of connectivity with external networks usually required to pass or request information and serves as an autonomous unit in the event this happens. Among the family of traceability networks existing, 4 main families can be established as so:

⁷⁸ "CAP Twelve Years Later: How the 'Rules' Have Changed." [Online]. Available: <http://www.infoq.com/articles/cap-twelve-years-later-how-the-rules-have-changed> (accessed in 01-05-14).

⁷⁹ Solving the Challenges of Big Databases with MySQL - <http://www.tokutek.com/wp-content/uploads/2012/11/big-challenges.pdf>



The difference between the four models comes from two factors:

1. Degree of centralisation of the orchestration of the request and queries;
2. Centralisation of the data itself;

In brief, the four models consist of:

- **One-up One-down** – Each actor will transmit the (legally) required information to the following, but also removing one level. This is the model currently recommended by the DQSA (Drug Quality and Security Act).
- **Centralised** – This model is monolithic and suits highly regulated implementation across a reduced set of actors. It is likely to pose some data management challenges, especially if the dataset is large to very large.
- **Cumulated** – The information is enriched by the actor of the supply chain as the product travels along. A recognised challenge with this kind of implementation is the increasing volume of the information as the product progress in the supply chain. This is still a concept that lacks a large-scale real-life implementation.
- **Distributed** – This is the kind of network usually for large-scale implementation with loose or no regulatory requirement such as farm-to-fork, Internet-of-things taxonomy. It does scale very gracefully in size and variety.

The nature of the problem at hand would suggest discarding a distributed architecture, due to data ownership consideration and the need for oversight. The principle of independence of the storage provider dictated by the wording of the Directive strongly indicates also a centralised model with Government oversight.

4.4.4 DETERMINING A MODEL SUITABLE FOR A TOBACCO TRACEABILITY

Several key-points are still lacking definition at this stage of the analysis, and having a holistic view of the system is insufficient to evaluate thoroughly the different architectures possible.

These points are:

- **Degree of Oversight & Involvement of Member States** – Each Member State is likely to have a different degree of involvement in the system. What are the minimum set of features and architecture possible to minimise the cost and maximise the effectiveness of the system? Which metrics will be applied to measure the correct implementation of the system? How will they be measured?
- **Operational Responsibilities** – As already mentioned, and even assuming the supply chain will be self-regulating, there is a number of situations that will require a close monitoring and subsequent intervention. Even if, at manufacturing level, the process can be largely automated, upper in the supply chain, part of the information regarding the chain-of-custody will require a person to wilfully *choose* to capture the information. Who are these persons and which autonomy will they have (the figure of the independent auditor probably under-estimates the effort required to such endeavour)?
- **Data Ownership** – The nature of the data transmitted by the EPCIS standard can be of sensitive commercial nature. Depending on the architecture chosen, part of this data is likely to transit across several trading partners that are not necessarily of the same alignment (e.g., the same logistic operator can provide services to two competing brands). Yet unclear is the extent to which the information received by the authorities can be used to deter illegal activity.
- **Consumer Role** – Even if the directive makes no mention of involving the consumer in the track and trace initiative, it would be legitimate to provide him the means to authenticate the product.
- **Impenetrability of the Supply Chain** (*especially leaking out*) – If the protection of legitimate businesses is taken for granted, to which degree the solution should prevent the leakage of legitimate product into the illegal market or channels (Internet sales, non-authorised cross border sales, etc.).
- **Choreography** – How and when the data moves? From capture to sharing? From sharing to checking? From checking to valid/invalid?

However, and according to the succinct analysis performed in 4.4.1, our preliminary recommendation for establishing criteria for the data-storage content of the study is as follows:

Functional Scope & Maturity

- EPCIS Compatibility & Extension
- Innovation
- Understanding of the Business Challenges
- Business Model/Cost effectiveness
- Vertical/Industry Strategy/Integration

Breadth of Experience

- Proven Product/Components
- Compliance & Information Security
- Architecture
- Data Governance
- Risk Management & Resilience

This is preliminary proposal only, to be used as a basis during the design activities of the EU Commission subsequent to this report.

5 TRACK AND TRACE SOLUTIONS CURRENTLY IN OPERATION

There are a multitude of track and trace systems in operation globally across a wide variety of industries. These systems have been implemented over time for different reasons and utilise different technologies. In identifying the appropriate benchmarks for tobacco, it is important to consider the application, business drivers and technologies most directly related to the problem statement as described in Section 2.

The following section, which is based on desk research and initial survey results, looks first at two case studies of tobacco track and trace solutions currently being used in the marketplace. This is followed by a brief background of track and trace in other industries that may be relevant to tobacco products. An outline of Tax Stamp programs throughout Europe is also included given the functional alignment to the Problem Statement (e.g., production validation, serialisation, secure marking). These case studies are aligned with and share some of the success factors identified in the TPD and are therefore relevant benchmarks with respect to a successful tobacco track and trace solution for the EU. (A complete analysis of each case study can be found in Annexure 3).

It is envisaged that following detailed discussions and follow up (and potential site visits) with select benchmarks, additional details and clarifications will be incorporated into the final report.

5.1 TOBACCO

The following are two track and trace solutions for tobacco products that are currently in operation, and are believed to be the most mature in terms of offering a traceability solution suitable for tobacco products:

- The SCORPIOS system used in Brazil for tobacco and beverage products; and
- The Codentify system developed and used by Philip Morris International (PMI) and endorsed by the four largest international cigarette companies under the banner of the Digital Coding and Tracking Association (DCTA).

The project was provided with comprehensive information on the operation of each solution. In the interest of protecting potentially commercially sensitive information, a brief summary of each is presenting in the following section.

5.1.1 SCORPIOS: SYSTEM FOR CONTROL, TRACK AND TRACE CIGARETTE PRODUCTION IN BRAZIL

In 2008, the Brazilian government implemented "SCORPIOS", a system to control, cigarette production. SCORPIOS is a production control system installed and operating on all cigarette manufacturing lines in Brazil. The system enables Brazilian authorities to authenticate and trace tobacco products back to point and time of manufacture

- For tobacco products exported from Brazil, a unique, secure and non-removable identification marking is affixed to each individual pack of cigarettes.
- Tobacco products consumed in the domestic market require a tax stamp, which incorporates a machine readable invisible marking that utilises secure ink for applying the unique code.

SCORPIOS has the following features:

1. Coding – Applies 2D Data matrix code that carries a unique serial number. This code is visible for exported products, and invisible for domestic products (where it is part of the tax stamp).
2. Distribution - Manages the distribution chain of tax stamps, allowing aggregation in packages, boxes and pallets, records all logistical movements and informs Brazilian authorities about the use of diverted stamps on controlled production lines or by an audit in the field.
3. Activation - Associates the unique tax stamp code to a pack produced for domestic market, registers the brand, the production line and the date and time of production.
4. Online Coding - Applies visible 2D Data matrix code on packs aimed for export. This encrypted code loads the date of production, the factory, the production line, the brand and a unique serial number.
5. Pack to Carton Aggregation - Cartons intended for export are also marked with 2D Data matrix visible code. During production, the carton code is associated with the N packs' codes contained in the carton (where N = 5, 6, 8, 10 and 12).
6. Centralization of Data - All information, including, coding, distribution, brand recognition, activation, aggregation and online coding are centralized in a central Data Management System central server. This system is administered by the Brazilian Mint (Casa da Moeda).
7. Management Reports - Centralized data allows the preparation of various management reports in real time, which support decision-making regarding the tax control of the Brazilian tobacco market.
8. Collaboration - Manages communication between the parties involved in the management, maintenance and use of Scorpios.
9. Audit - Verifies the authenticity of a domestic tax stamp and of the virtual export stamp and allows tracking the pack or carton through the time of production.

The Brazilian Government has since expanded the Scorpios solution to also securely mark and trace alcohol and soft drink products.

COMMENTARY

The Brazilian system is based on legislation and is controlled and managed by the Government. The solution primary objective is tax verification and manufacturer compliance monitoring, and therefore includes additional components beyond tobacco traceability. Some highlights of the solution include:

- SCORPIOS combines the traceability solution with security inks to create a secure mark. By combining security features with the unique identifier, it combats attempts by illicit operators to reproduce codes and apply legitimate codes onto illicit products.
- Reduced impact on operators during shift start procedures by automatically reading retail barcode (EAN/UPC) to determine Brand and Product SKU (and image recognition in case of beverages) recorded in the unique identifier.
- Multiple integrity checks, validations and reconciliation measures are incorporated in the manufacturing process to ensure the solution is operating correctly.
- Scale advantage in terms of operation, monitoring and maintenance. Further, continuous solution monitoring and proactive maintenance minimises intrusion of the solution on manufacturers.

Some concerns related to the fit of the solution in the TPD context:

- Additional production control elements and use of an independent solution provider is anticipated to have cost implications on manufacturers.
- The current implementation in Brazil does not track tobacco products beyond point of tax payment, which is the manufacturer. Tracking beyond this point would require additional development.

5.1.2 CODENTIFY: THE SYSTEM ENDORSED BY THE FOUR LARGEST INTERNATIONAL TOBACCO COMPANIES

Codentify® is a Code Verification Solution (CVS) created by Philip Morris International (PMI) to record and access traceability information related to tobacco mastercases, cartons and cigarette packs. Codentify is now endorsed and promoted by the Digital Coding and Tracking Association (DCTA), which is made up of British American Tobacco (BAT), Imperial Tobacco Group (ITG), Japan Tobacco International (JTI) and PMI.

Codentify is a code assignment module uses a unique, ciphered 12-digit alphanumeric code printed by visible ink both directly, on each cigarette pack, as well as onto a self-adhesive label that is consequently attached to each carton or other form of cigarette outer case.

A coder placed on each cigarette production line generates the code after receiving authorization, or a “key”, from a key generator. The key generator is under the control of the brand holder using Codentify.

The coder also receives specific information like the ID of the cigarette production line, brand of cigarettes that shall be manufactured, etc. The codes are consequently generated and printed or attached to each cigarette product. Initial Codentify implementations printed only a human readable alphanumeric codes on packs. However, more recent Codentify implementations have incorporated a machine readable code based on the AIM ISS Dotcode specification⁸⁰, in addition to printing the human readable code.

For cartons, master cases and pallets, the unique identifiers are based on typical GS1 compliant identifiers (i.e. non-encrypted serialised codes) with each manufacturer able to specify the relevant detailed coding structure.

Verification requests can be initiated by various parties via differing channels (e.g., via web, e-mail, fax, SMS or call centre) that are specific to each market where it is (or is to be) implemented. The solution can be implemented to allow the verification centre to check the code through the code checker, informing the inquiring party if the code is valid or false and on which kind of product it should be printed or attached. Counterfeited codes are detected when the code is verified several times.

Codentify by itself is not a **secure marking** solution and includes no safeguards to prevent valid codes from legitimate packs being duplicated onto unauthorised tobacco packs as it relies on the assumption that counterfeiters are unable or unwilling to re-engineer valid codes or acquire large numbers of valid codes so that these can be used for printing on counterfeited products. At the same time, if counterfeiters decide to re-print valid codes on counterfeited production, Codentify relies on the assumption that the intensity and frequency of verification requests will be high enough to spot that the same code is being reported and they will “catch” the counterfeit product. Given standard

⁸⁰ Association for Automatic Identification and Mobility (AIM) members include manufacturers, distributors, resellers and end-users of barcode, RFID, related technologies and mobile computing solutions. DotCode is a rectangular matrix symbology designed to produce machine-readable coding suited for high-speed industrial inkjet and laser marking equipment.
Website: <http://aimglobal.site-ym.com>

practice with respect to enforcement models and statistical significance and number of validations required, this assumption may be weak.⁸¹

According to the four manufacturers⁸², the Codentify and marking system for **pack, carton**, and master case to pallet is operational on 5% of the ±770 production lines in the EU, but the number of operational production lines is steadily increasing as the solution is rolled out.

COMMENTARY

The tobacco industry's Codentify solution provides a standard mechanism for manufacturers to generate unique identifiers for tobacco packs / items (and potentially cartons) in a consistent manner that ensures uniqueness. Downstream, manufacturers have independence as to the solutions used for recording traceability processes (aggregation and marking of secondary and tertiary packaging). Some highlights of the solution include:

- Low cost to the manufacturers (primarily initial CAPEX for the equipment – thereafter the cost of marking (ink))
- The code generator cleverly uses data elements inherent in the production process (e.g. production line, date and time of manufacture). Further, the algorithm for code generation offers an ability to smartly reduce the data storage requirements.
- The system is implemented and maintained by the tobacco manufacturers themselves giving them choice and control of their production process (and costs) related to traceability
- Solution, as advocated by DCTA, provides interoperability by using industry standards (GS1) for markings on cartons, master cases and pallets.

Some concerns related to the fit of the solution in the TPD context:

- Risk is that the system might not provide reliable guarantees for independent control and management of the codes at pack level.
- Limited scale advantage – each manufacturer pioneers and develops own expertise to develop and operate the traceability solution.

5.2 TRACK AND TRACE IN OTHER INDUSTRIES

A summary of track and trace solutions in operation in various industries is presented below. Additional information on these case studies can be referenced in Annexure 3.

PHARMACEUTICALS

The global pharmaceutical industry is currently facing massive problems with counterfeiting, theft, channel diversion and false returns to manufacturers. Companies that operate within the industry and governments worldwide promote using product serialization as they believe it significantly reduces counterfeiting, given the use of a unique serial number that identifies the product, in addition to origin, batch number and its expiry date. The objective is that serialization will allow the product's lifecycle to be traced from production, through distribution and finally to dispensation to patients at the drugstore/pharmacy or hospital.

⁸¹ Based on internal working paper of statistical modeling conducted by the project with respect to a generic customs/revenue enforcement scenario. Further statistical modeling in accordance with the EU enforcement context (which differs from Member State to Member State) would be required to further elaborate on this conclusion.

⁸² Feedback from engagements with four tobacco manufacturers (members of DCTA) in 3rd quarter 2014

Countries throughout the world are working towards implementing legislation and solutions that aim to achieve value chain-wide tracking and tracing of products, including the EU, the United States, China, Turkey, India, Korea Argentina and Brazil.

In the EU, Directive 2011/62/EU introduces mandatory 'safety features' to allow the verification of the authenticity of medicinal products using a 'unique identifier.' A concept paper was launched in November 2011 for public consultation. The European Federation of Pharmaceutical Industries and Associations (EFPIA) and the European Directorate for the Quality of Medicines and HealthCare (EDQM) created recommendations:

- Using GS1 Standard and the 2D Matrix Code
- Using national identifiers according to national law
- Using a central hub or central system to control

The data encoded in the unique marking applied to pharmaceutical packs includes: product code, serial number, expiration date, and lot number (batch code).

EXPLOSIVES

The risk of explosives to fall into the hands of terrorists and the threats of terrorism attacks led many countries, including the EU to adopt security measures for explosives in all stages of the supply chain.

In the EU, the mandatory data required on these products are the origin (country and site code – 5 digits) as well as a serial unique identifier (15-30 digits). Additionally, but not compulsory, the Federation of European Explosives Manufacture also recommends taking advantage of this legal imposition to store additional business data⁸³ such as Stock Keeping Unit SKU (up to 35 digits), Batch Number (up to 20 characters) and Unit of Measure (in practice, up to 3 letters).

WINE

Counterfeit wines are estimated to account for as much as five percent of the market.⁸⁴ Identifying counterfeits is a matter of public health. It is also a matter protecting legitimate wine makers around the world whose businesses and reputations are being negatively affected and damaged when counterfeits of their brands reach the consumer.

In 2003, GS1 co-established the Wine Traceability Working Group together with the British Wine and Spirit Association (WSA) and its French counterpart - Association Française des Eleveurs, Embouteilleurs et Distributeurs de Vins et Spiritueux⁸⁵. The objective was to adapt the GS1 System for implementation by the wine industry to facilitate compliance with the traceability-related provisions of the General Food Law - Council Regulation (EC) No. 178/2002.

GS1 recommends using the following GS1 Traceability Tools in the context of wine:

- Global Location Number - numeric code that identifies company or physical entity
- Global Trade Item Number - number used for the unique identification
- Serial Shipping Container Code - a number used for the unique identification of logistic units

⁸³ <http://feem.info/wp-content/uploads/2013/01/Guidance-Note-FEEM-European-Code-Structure-Mod.1-April-2013.pdf> (accessed 22/04/2013).

⁸⁴ Wine Spectator

⁸⁵ http://www.gs1.org/docs/traceability/GS1_wine_traceability.pdf

- Application Identifier - variable information, such as a batch number, production date or customer purchase order. This information is bar coded in the GS1-128 bar code symbol.
- Bar Codes and RFID - GS1 bar codes allow automatic data capture of GS1 numbers

TOYS

There have been numerous cases in recent history regarding unsafe, dangerous toys getting into the consumer market, e.g. in 2007 Mattel had to recall 1.5 million products because toxic lead paint was found on its toys. Many countries have implemented legislation regarding tracking and tracing toys and have instituted "recall" systems to assist in quickly getting dangerous toys off of the market. The following outlines the requirements for the EU and the United States.

EU legislation requires manufacturers to meet the following requirements:

- Name,
- Registered trade name or registered trade mark and
- The address at which they can be contacted,
- A type, batch, serial or model number or other element allowing their identification,
- On the product or, where that is not possible, on its packaging or in a document accompanying the product,
- That will allow it to identify any economic operator who has supplied them with a product and any economic operator to whom they have supplied a product ("one up, one down").

Importers are required to indicate the following elements:

- Name
- Registered trade name or registered trade mark
- Address at which they can be contacted, on the product or, where that is not possible, on its packaging or in a document accompanying the product

The recall of consumer products such as toys in the EU relies on the RAPEX (the EU Rapid Information System for non-food products). This system allows EU Member States and the European Commission to share information quickly and efficiently about dangerous products found on the European market and to inform consumers about potential risks to their health and safety.

5.3 TOBACCO TAX STAMP & FISCAL MARKING PROGRAMMES IN OPERATION IN THE EU

Tax stamps provide a form of Government control over tobacco manufacturing and tobacco products made available on the internal market, and existing tax stamp programmes are therefore an important consideration for the project.

Authentication features used for tax stamps suitable for tobacco products provide a useful foundation for understanding and experience in terms of security features relevant to TPD Article 16. There are several shared objectives in terms of authentication:

- Tax stamps have evolved to include security features for authentication by different user groups, 1) provide a reliable overt mechanism for consumers and

members of the public, and, 2) provide additional covert features suitable for enforcement agencies.

- Need to be resistant to attempts at manipulation, imitation and reproduction.
- Technologies and application methods need to be suitable for tobacco products and generally minimise impact on tobacco manufacturers
- Fulfil requirements of Government stakeholders, beyond the brand protection of the tobacco manufacturer; and
- Need to be cost effective.

5.3.1 SUMMARY OF CURRENT PROGRAMMES

Tobacco tax stamps are a prevalent fiscal control used by EU Member States as both a volume and market control mechanism to control the payment of Excise taxes. A summary review conducted by the project showed that **23 of the 28 Member States use tobacco tax stamps**. Using available tobacco volume data for EU Member States, analysis shows that some 23 billion tax stamps are applied to tobacco products each year in the EU, or approximately 80% of total licit tobacco packs.

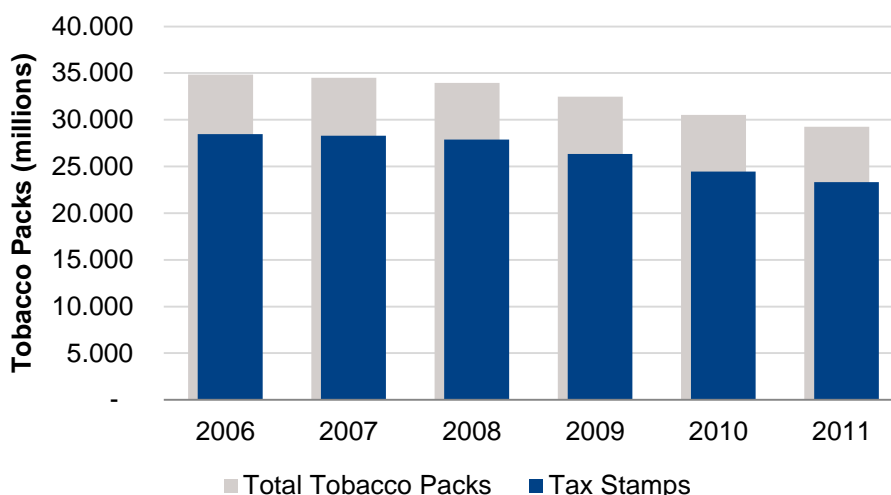


Figure 30 - Comparison of Total Number of Tobacco Packs produced and Number of Packs subject to a Tax Stamp/ National Identification/ Fiscal Marking

Review of the existing tax stamps reveals that several of these include variable data including serial numbers and 2D data matrices. However, it is believed that these serial numbers are used for traceability and control of the security features up to the point of application by the manufacturer, and that the tax stamp is not used for tracking and tracing of tobacco products through the distribution chain.

A summary of the research showing tax stamp programmes active in each member state can be referenced in Annexure 4.

6 METHODOLOGY FOR MARKET ASSESSMENT

The domains of track and trace and security feature technology solutions are vast and complex, given the multitude of different technologies and solution providers it encompasses. Furthermore, since track and trace is a relatively new and emerging practice in supply chains (particularly with respect to product-level track and trace) there is a lot of marketing activity but far less operational activity (e.g., goods actually being tracked and traced in the supply chain). For example, with respect to the tobacco industry, a high proportion of market participants advertise leading track and trace technologies, whilst actual implementation experience may be limited or even missing. The market and solution analysis needs to take these dimensions into account.

The market assessment methodology consisted of four steps:

- 1 **Market Research:** Research was conducted with respect to relevant industry publications and trade/industry associations to identify potential participants for inclusion in the analysis. Extensive web-based searches were conducted and direct contact was made via telephone and email to invite participants and establish the right contact points within the various companies.
- 2 **Survey Preparation:** A detailed survey was developed in accordance with the Problem Statement and related key defining parameters (e.g. FCTC Protocol). Additionally, this step included key inputs from relevant technical standards. The survey was prepared in such a way as to be a combination of structured responses as well as free form in order to maximise the accuracy of the responses. The Commission was given the opportunity to review, comment and approve the final survey that was sent to invitees.
- 3 **Execution:** Refers to the actual market survey whereby questionnaires were sent out to the selected population. Contact was established with participants throughout the survey period to encourage responses.
- 4 **Analyses:** Consisted of consolidating the data (responses) in order to analyse the information collected. Initial scoring was done by Team members and peer reviewed to ensure consistency. Final scoring and criteria weighting was conducted via Team workshops where key issues and criteria were vetted in detail and consensus was reached among the analysis Team.

The approach and methodology employed was inclusive of all “known” (based on research) relevant technology and solution providers. Given the alignment of the market subjects to the Problem Statement, the Team is confident that no relevant market players have been omitted in the overall process.

6.1 OVERVIEW OF METHODOLOGY: ASSESSMENT MATRIX

As outlined in the technical proposal and agreed upon during the project kick-off meeting, the underlying approach to analysis employed an Assessment Matrix. The approach uses a visual graphic (see below) and a uniform set of evaluation criteria, allowing one to quickly digest how well technology solutions are executing against their

stated vision. The Assessment Matrix has similarities to the Magic Quadrant approach in the information technology domain and considered in academic literature⁸⁶. Organisations use such visual representations that provide a market overview as first step to understanding the technology solutions they are considering for investment opportunities or projects.

The Assessment Matrix considers two primary dimensions:

- **Functional Scope & Maturity:** The degree to which the proposed solution offering provides the necessary functional components for a traceability solution suitable for tobacco products, the understanding of traceability requirements, and fit to the problem statement.
- **Breadth of Experience:** Consideration of existing implementations and experience implementing, operating and maintain required solution components.

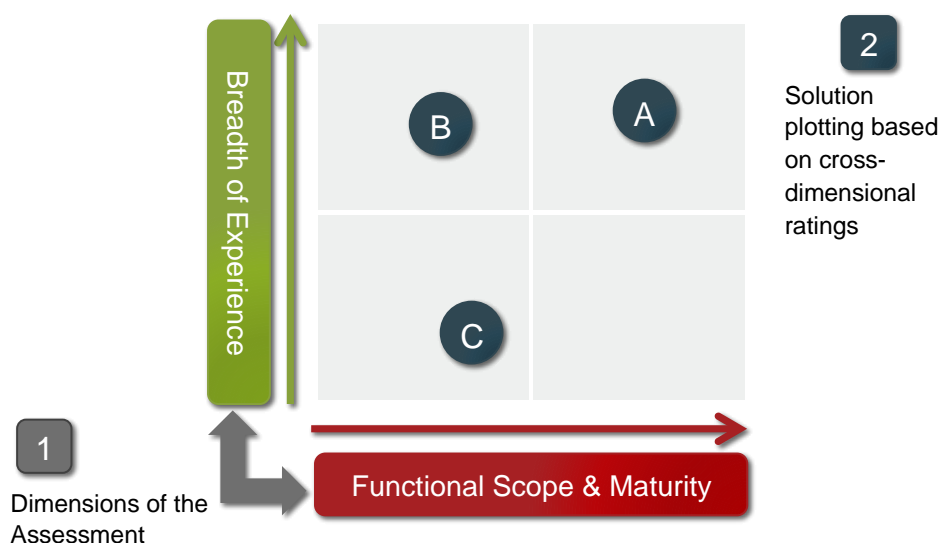


Figure 31 - Graphical Representation of Assessment Matrix Dimensions

6.2 DEVELOPING THE ASSESSMENT MATRIX

The Assessment Matrix and the dimensions it espouses are described in Section 6.1 above. In the Assessment Matrix approach, multiple evaluation criteria are applied to assess each dimension, and to enable feature and performance comparisons between solutions. Each track and trace solution is evaluated against these criteria, and the results are then visually graphed to provide a summary of the market and relative position of the solution options (both within a respective industry or across industries).

⁸⁶ Neil Pollock et Robin Williams, « The sociology of a market analysis tool: How industry analysts sort vendors and organize markets », *Information and Organization*, 2009, vol. 19, no 2, p. 129-151.

6.2.1 DIMENSIONS AND EVALUATION CRITERIA

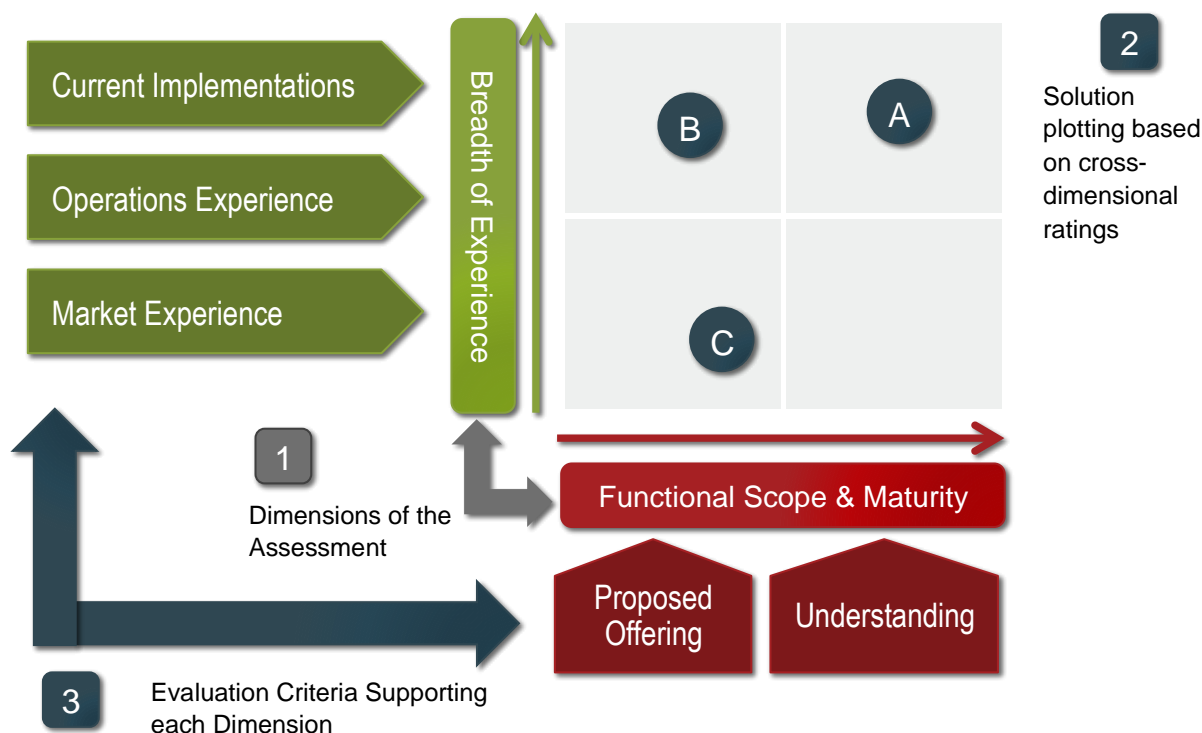


Figure 32 - Graphical Representation of Evaluation Criteria on Magic Quadrant

In order to rate solution providers against each dimension, evaluation criteria had to be defined which would form the basis for the research questionnaire. The evaluation criteria were structured as follows:

Functional Scope & Maturity:

- **Proposed Offering:** The extent to which the solution proposed by the organisation addresses each of the main identified components required for traceability system aligned to the problem statement and critical success factors identified in Section 2.
- **Understanding:** Consideration by the solution provider of those additional factors required to offer a tobacco control solution operating at this scale. This includes understanding the importance of open standards for information exchange to minimise the impact on industry, and recognising the wealth of tobacco movement information being collected and how this could better assist EU authorities with their respective mandates.

Breadth of Experience:

- **Implementation Experience:** Assessment of experience gained by the solution provider from current implementations. Considers whether the solution uses proven components, the number of implementations and operational sites, and the extent to which the industries for which the solution has been implemented share similarities with the domain of tobacco.
- **Operations Experience:** The experience of the solution provider in terms of day-to-day experience operating and supporting an implemented solution.

- **Market Experience:** Consideration for diversity of experience obtained through operating track and trace solutions in more than one industry, as well as the number of years in operation.

6.2.2 EVALUATION SUB-CRITERION

Each sub-criterion was rated⁸⁷ based on the level with which it met the evaluation criteria. However, in order to properly rate these sub-criteria, evaluation factors were defined for each. These factors guided the rating process by relating them to specific questions and importantly to the requirements upon which the criterion is based. The table below shows an example of how the factors were defined.

#	Marking and Tracing of Tobacco Products Question	Requirement Origin	Evaluation Factors
A	Serialisation of items		<ul style="list-style-type: none"> ▪ Identifier is obfuscated and sequence is unpredictable ▪ Unique identifier (complete) to be generated at the time of manufacture (in order to record time, manufacturer line). Components of unique identifier (e.g. unique key) may be generated and assigned ahead of time ▪ Speed – need to be generated fast enough to support production lines (minimum 1,000 per minute) ▪ Efficiency of encoding mechanism ▪ Secure mark makes allowance to maintain uniqueness for active tobacco packs – considers total number of marked items (within EU for product lifecycle) (Total packs in the EU) ▪ Mechanisms in place to combat against “rogue” manufacturers / importers ▪ Secure mechanism for unique identifier generation at source (either proprietary or safe-guarded) (e.g. <i>Kerckhoffs</i> principles, <i>Shannons</i>’s maxim of safekeeping encryption keys, not the encryption algorithm)
	<ul style="list-style-type: none"> ▪ 5) Describe the unique identifiers that will be used on tobacco products, how they are generated, what makes them unique, and what controls ensure they are unique. 	Article 14: Traceability Solution Understanding Suitability for Industry context	
	<ul style="list-style-type: none"> ▪ 6) Describe any controls used to limit generation of unique identifiers (serial numbers) to authorised parties only. 	EU Problem Statement: Compliance considerations	

Table 21 – Evaluation Sub-Criterion Factors

The full table containing the sub-criterion and evaluation factors can be found in Annexure 6.

6.3 MARKET SURVEY SCOPE AND ASSESSMENT CRITERIA

This project used a **survey-based research** component to obtain information from the track and trace and security feature industry directly, and this data was used to prepare the solution landscape, outlining the available solutions and providing a mechanism to assess and compare the details of each. The design of the assessment was to obtain specific, focused responses about the latest security features and technology in the market that went beyond the information available for public knowledge on the organisation’s website.

6.3.1 MARKET SURVEY SCOPE

The project prepared a list of solution providers for Traceability and Security Features solutions that were identified in the areas of track and trace, brand protection, security printing and fiscal markings for tobacco and alcohol control. Sources included media articles, research reports, technical papers, case studies and available online “attendance lists” from conferences.

In total, **274 organisations** were identified as potential candidates for participation in the market survey. These organisations ranged from providers of one security feature to providers of full track and trace solutions. It also included State Printers providing tax stamps with track and trace technology. The organisations were primarily from North

⁸⁷<http://en.wikipedia.org/wiki/Rating>

America and Europe, with a few from South America and Asia. The list of organisations ensured representation from all types and sizes of security feature organisations. For reference, the list of organisations that were identified is provided in Annexure 5 of this document.

6.3.2 OVERVIEW OF SURVEY PROCESS

The survey research was conducted electronically using an online survey tool, *SurveyGizmo*. Participants included both established and emerging providers of technologies and solutions in the track and trace and security feature domains, identified during the desk-based research referred to above. This list of survey participants was augmented with online email contact information, and each participant was sent an invitation containing a unique identifier to complete the survey online. Participants were provided 4-6 weeks to complete the survey, with a follow-up reminder email sent to those participants that had not completed the survey after the first 2 weeks.

IDENTIFICATION AS A CHAFEA CONTRACT

The project managed the communication lists, survey responses and generated the email messages. However, reference was made to the "EAHC⁸⁸ Project email address", included on survey correspondence. It was agreed that from an external industries' perspective – the use of an official European Commission email address, together with a summary cover letter provided by CHAFEA would add credibility to the research and it is anticipated this would increase the response rate. The CHAFEA letter indicated authorisation for Eurogroup Consulting (Portugal) and Sovereign Border Solutions (SBS) to conduct the survey, and provided assurance that survey responses would be treated in strict confidence. This authorisation and confidentiality assurances were essential given the nature and detailed coverage of solution components within the survey.

ACTIVE ENGAGEMENT ENCOURAGES SURVEY PARTICIPATION

Eurogroup Consulting and SBS staff contacted each of the organisations individually by phone or email from contact information either provided on the organisation's official website, from CHAFEA contacts or through Eurogroup Consulting and SBS contacts. Eurogroup Consulting and SBS attempted to contact each organisation between 3-4 times in an effort to get an email or phone number of the person who would be able to thoroughly complete the assessment. Continuous contact was made over several correspondences (staggered over a number of days and weeks) to ensure the correct person was contacted and that they completed the assessment in a timely manner. Many of these correspondences were translated and sent in the organisation's home country language. If a contact name was not provided, the assessment was sent to an email provided online either in the sales, marketing or administrative departments.

Of the 274 identified participants, contact information was obtained for 267, and a survey link was distributed to these organisations. Organisations were given between 4-6 weeks to complete the assessment, with numerous reminders sent to ensure they completed the assessment. An organisation only completed the questions relevant to its operations. The assessment also gave the respondents an opportunity to attach additional files to support their responses recorded online.

A number of the organisations did not respond to any of Eurogroup Consulting and SBS's attempted contacts. Many of the organisations contacted declined to participate because they were either not interested, were concerned about privacy issues, were concerned

⁸⁸ The name of the agency was changed during this same period from: "Executive Agency for Health and Consumers (EAHC)" to "Consumer Health and Food Executive Agency (CHAFEA)".

they were at risk if their security features were not prioritized, did not have the adequate staff to complete the assessment, did not feel that had the knowledge capacity to complete the assessment or did not supply the security features for tobacco and did not want to take the time to complete the assessment.

6.3.3 SURVEY RESPONSE RATE

The survey response rate shows a high falloff – from the group of 267 participants that were successfully contacted, the online survey was viewed 165 times, of which only 76 participants continued beyond the second page. In total, 42 completed survey responses were received, approximately 15% of total participants identified. The respondents included a mix of both established and emerging organisations.

Respondents were asked to categorise which solution components they would be able to provide feedback covering the areas, and each category was well represented with some 80% of respondents offering a solution for track and trace, over three-quarters of respondents indicating they were providers of Track and Trace solutions, and little more than half were providers of the accompany data storage components.

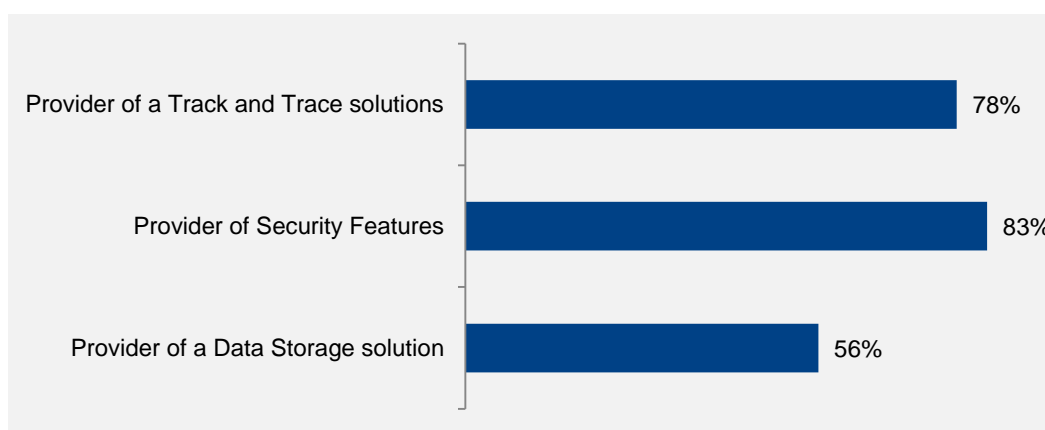


Figure 33 - Survey components completed by Respondents

The following section of the report presents the analysis of the survey response using the modified magic quadrant. Once the survey was executed, the analysis phase began. The following section describes the steps that were followed in order to achieve this.

6.4 ASSESSMENT MATRIX SCORING APPROACH

The solutions under evaluation have been categorised as the Traceability (Track and Trace) solution and Security Features solution. In order to evaluate these solutions independently, the Assessment Matrix approach described above has been repeated for each using an evaluation tool in Excel specifically built for this purpose. This implies that separate evaluation criteria and sub-criterion, weightings, ratings and resultant scoring were applied for each in order to present tailored solution views.

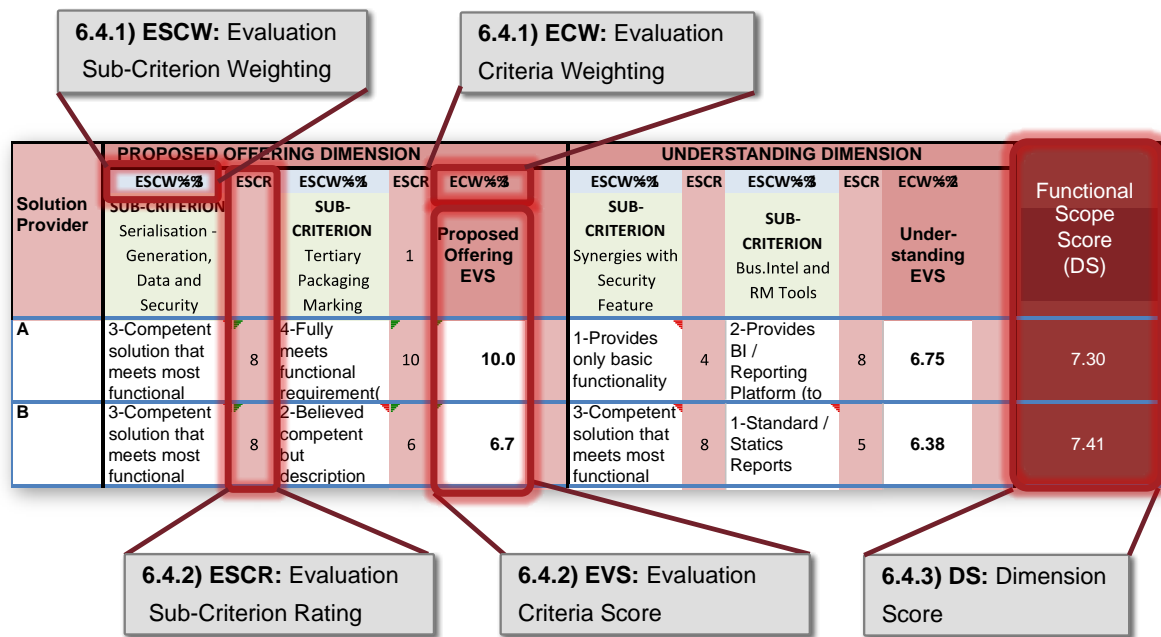


Figure 34 - Evaluation Tool Overview

The evaluation tool that has been developed is merely a structured way to achieve the Assessment Matrix by allowing the Team to:

- Capture the survey responses consistently;
- Structure the responses according to the evaluation criteria;
- Apply weightings at multiple levels:
 - Dimension
 - Evaluation criteria
 - Sub-criterion
- Rate accordingly; and
- Calculate scores for each entity per dimension and thus solution.

The aim of such weighting, rating and scoring per dimension is to remove any potential subjectivity of the evaluators whilst applying a statistical approach to determining the Assessment Matrix score for each respondent. This score is the basis for the graphical representation on the Assessment Matrix.

6.4.1 WEIGHTINGS PER EVALUATION CRITERIA AND SUB-CRITERIA

Weighting: Statistical technique in which a data item is emphasized more than other data items comprising a group or summary. A number (weight) is assigned to each data item that reflects its relative importance based on the objective of the data collection.

As defined above, weightings were applied to the evaluation criteria and sub-criterion in order to emphasize the importance of certain criteria over others. The approach to apply

these weightings⁸⁹ was primarily based on the domain expertise and knowledge of the Team as well as the insights gained during the study and the final review was based on workshop consensus. A generic 1 -3 scale was applied, with 1 being least applicable and 3 being most applicable.

Referring to Figure 34 above, the specific weightings are defined as follows:

ECW: Evaluation Criteria Weighting: the weighting applied to the evaluation criteria

ESCW: Evaluation Sub-Criterion Weighting: The weighting applied to each specific sub-criterion

6.4.2 RATINGS PER EVALUATION SUB-CRITERION

Rating: A rating is the evaluation or assessment of something, in terms of quality or quantity or some combination of both.

This rating⁹⁰ was initially done by a single resource that possessed the most domain knowledge in that particular area and was most familiar with the evaluation criteria and approach. The Team then caucused the ratings and applied a collective consensus approach to determining the relevance and accuracy of each. The resultant rates were scored on a scale of 1-10. A rate of 1 being the least close to the evaluation criteria and 10 being the closest to the evaluation criteria.

Figure 34 above, the specific ratings are defined as follows:

ESCR: Evaluation Sub-Criterion Rating: the rating applied to each sub-criterion

Once the sub-criterion was rated, the sum of these ratings was multiplied by the weighting of the applicable evaluation criteria in order to determine the evaluation criteria score.

Evaluation Criteria Score (EVS) =

SUM [Evaluation Sub-Criterion Rating (ESCR) X Evaluation Sub-Criterion Weight (ESCW)]

EVS: The score for the respective evaluation criteria.

6.4.3 RESULTANT SCORE PER ENTITY

The application of the weighting and rating of each evaluation criteria provided a cross section calculation for the scoring of each entity (Solution Provider).

The Dimension Score is calculated using the following formula:

Dimension Score (DS) =

Sum[Evaluation Criteria Score (EVS) X Evaluation Criteria Weight (ECW)]

⁸⁹ <http://www.businessdictionary.com/definition/weighting.html>

⁹⁰ <http://en.wikipedia.org/wiki/Rating>

The specific ratings are defined as follows:

- **DS:** Dimension Score: calculated score based on inherent weightings and scores of associated evaluation criteria.

This score was then plotted onto the Assessment Matrix to provide a graphical view of each respondent against the defined dimensions of Functional Scope & Maturity and Breadth of Experience. This graphical representation of the scores is further explained in Section 6. The remainder of this section seeks to describe the evaluation criteria for each solution independently.

6.5 TRACEABILITY SOLUTION EVALUATION CRITERIA AND SUB-CRITERION

In order to understand and rate each evaluation criteria effectively it was required to further distil each into sub-criterion.

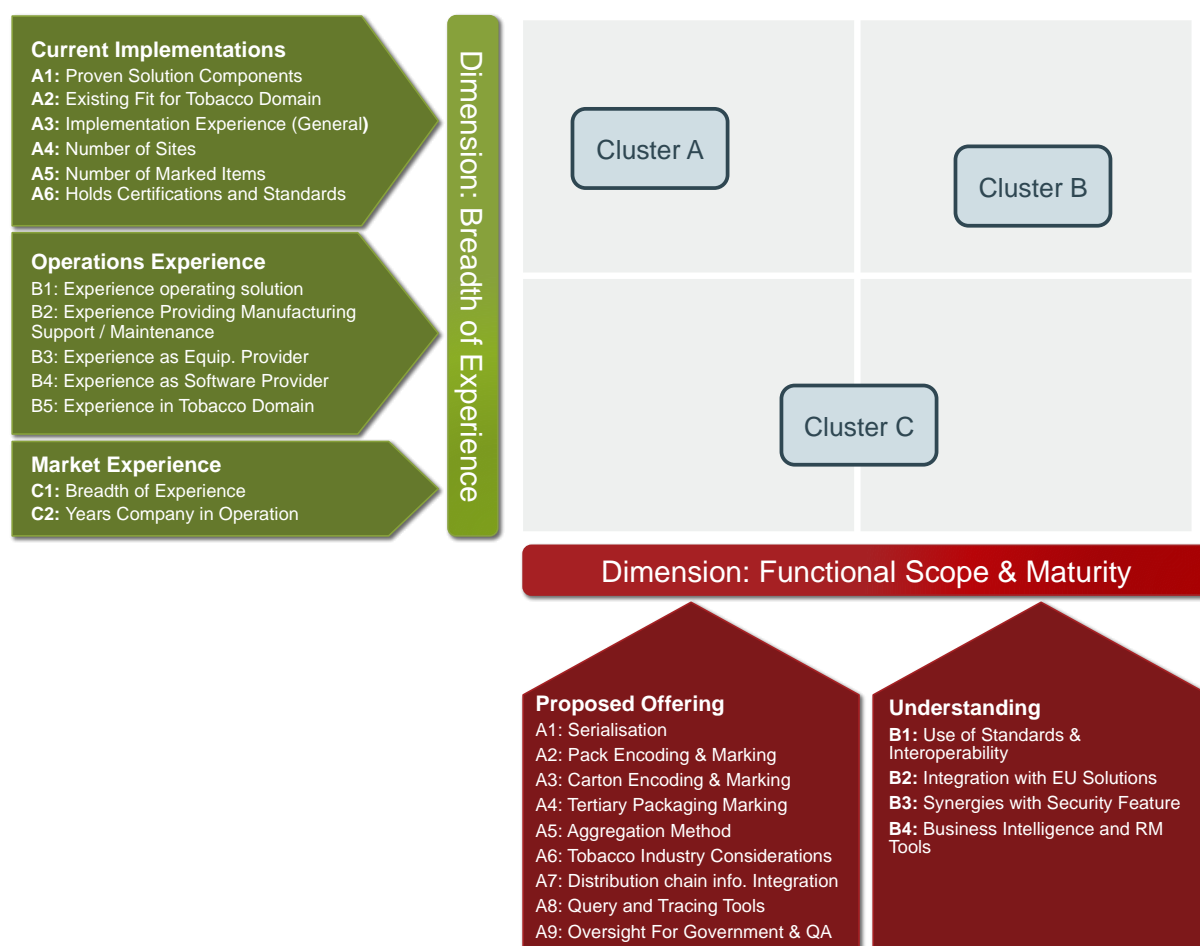


Figure 35 – Traceability Evaluation Sub-criterion

These sub-criterions represented the level of detail against which each track and trace solution was evaluated. The tables below describe the evaluation in more detail and display the determined weight for that particular Criteria and the related sub-criterion. The criteria and evaluation factors were prepared with reference to the Problem Statement and Traceability Solution Critical Success Factors identified in Table 7 in Section 2.4.1 above.

The functional scope & maturity axis consists of two primary dimensions: 1) The proposed offering of the solution provider, and 2) Level of understanding. The table below describes the evaluation in more detail and displays the determined weight for that particular Criteria and the related sub-criterion. Also, the proposed weighting of each item has also been included.

TRACEABILITY - DIMENSION: Functional Scope & Maturity		
Sub-Criterion (Weight)	Description	
Criteria A. Proposed Offering (Weighting: 2)		
A1: Serialisation - Generation, Data and Security	3	<ul style="list-style-type: none"> ▪ Solution employs a secure method for generating the unique identifier that is accessible to authorised parties only. ▪ Unique serial number has scope for tobacco market (~30 bn packs annually and in field for 4 years would require some 120 bn unique items). ▪ Flexibility to allow additional data to be included as part of the unique identifier (i.e. data that can be decoded without accessing an online database such as the identification of the manufacturer). ▪ Generation method should be compatibility with requirements for direct marking. Therefore, solution should provide mechanism for numbers to be securely transferred or generated to the production line at the time of application to tobacco packs. ▪ Unique identifiers are secure, meaning they are encrypted, and the sequence is unpredictable.
A2: Pack Encoding and Marking	3	<ul style="list-style-type: none"> ▪ Considers both: <ul style="list-style-type: none"> - The symbology (or carrier) used to encode the unique identifier and associated data; and - The physical method the mark is printed or applied to the tobacco pack. ▪ The marking should be permanent and attempts to remove or tamper with the mark should damage both the pack and mark. The location and marking method must allow the unique identifier to remain readable after the tobacco pack has been opened. ▪ The solution should provide a quality control mechanism to inspect that readable marks have been applied to all tobacco packs. ▪ Should include a component that is compatible with industry standards for interoperability / mark reading across EU Member States
A3: Carton Encoding and Marking	2	<ul style="list-style-type: none"> ▪ Similar to tobacco packs, this considers the symbology used to encode a unique identifier and other data, together with the physical method that tobacco cartons are marked / printed. For flexibility, solution should support either a machine readable and / or a human readable component. ▪ The solution should include a quality control mechanism to ensure that readable marks have been applied to all tobacco cartons. ▪ A component that is compatible with industry standards for interoperability / mark reading across EU Member States.

TRACEABILITY - DIMENSION: Functional Scope & Maturity		
Sub-Criterion (Weight)		Description
A4: Tertiary Packaging Marking	1	<ul style="list-style-type: none"> ▪ Considers the proposed symbology and method for marking / printing the unique identifier on master cases and pallets (referring to packages within which packs and cartons are packed). ▪ The solution should be compatible with existing standards for consignment marketing (such as Data matrix and GS1-128 barcodes) at this level, and the solution should support either a machine readable and / or a human readable component.
A5: Aggregation Method	3	<ul style="list-style-type: none"> ▪ Refers to the Method, which the solution identifies and records the unique identifier of each of the tobacco packs that have been placed in a tobacco carton, and associated with the unique identifier of the carton. Similarly, the relationship between cartons and mastercases needs to be identified. ▪ The solution should support aggregation both at the data level (being able to record this type of "parent-child" relationships between items), as well as a robust physical method of recording the items (e.g. a vision system, or other validation system, that scans which items were placed in the parent container).
A6: Tobacco Industry Considerations	3	<ul style="list-style-type: none"> ▪ Assesses the extent to which the solution considers requirements of the tobacco industry within the EU: <ul style="list-style-type: none"> – Support for both large highly automated manufacturers, as well as less automated smaller operators – Consideration for marking tobacco products manufactured within the EU, as well as imported products ▪ Considers existing production line equipment, maintenance requirements and production line support for manufacturers.
A7: Distribution chain information Integration	2	<ul style="list-style-type: none"> ▪ Ability of the solution to receive distribution chain event information from 3rd party systems. Recognising the vast number of supply chain operators (wholesalers, distributors, etc.) in the EU (several that deal in both tobacco and non-tobacco products), this would allow the solution to co-exist with large ERP, warehouse management and logistics systems already deployed.
A8: Query and Tracing Tools (for EU and Member States)	2	<ul style="list-style-type: none"> ▪ The type and sophistication of mobile tools offered by the solution provider for EU authorities to read markings on packs, cartons, mastercases and pallets to obtain manufacture and distribution chain information. ▪ This dimension also assess the extent to which the solution considers potential requirements for EU/Member state authorities performing product scanning and tracing in the field.
A9: Oversight For Government & QA	2	<ul style="list-style-type: none"> ▪ Recognises the requirement for a tobacco control solution that offers functions to aid oversight of tobacco manufacturing and distribution chain for EU authorities understanding that capacity for this function is precious. ▪ Solution functions that are provided for monitoring the traceability data and events to identify and alert anomalous flows, unidentified products and/or diverted tobacco products, reconciliation services (between events and data sources), functions that provide oversight of manufacturing activity and monitoring distribution chain events. Therefore, does the solution consider the objectives of a traceability system, that amongst other items, includes protecting the function of the internal market and combatting illicit trade.

TRACEABILITY - DIMENSION: Functional Scope & Maturity		
Sub-Criterion (Weight)	Description	
Criteria B. Understanding (Weighting: 2)		
B1: Use of Standards and Interoperability	2	<ul style="list-style-type: none"> Organisation understands importance of open standards and interoperability. Solution support for established industry standards in terms of carriers (e.g. GS1-128, 2D Data matrix) and exchange and storage of logistic event information (e.g. EPCIS messages and EPCIS-compliant repositories).
B2: Integration with EU Solutions	2	<ul style="list-style-type: none"> Solution providers recognises opportunities for integration of their solution offering with EU movement control solutions to support import, exports and transit controls (e.g. reconciliation and acquittal of EMCS transactions).
B3: Synergies with Security Feature	1	<ul style="list-style-type: none"> Opportunity for Solution Provider to indicate how tobacco tracing solution components could complement / enhance the functioning of the security feature (Article 16 of TPD). Synergies could include synergies with production line equipment to provide cost-savings and/or provide opportunities to detect potential non-compliance and enhance traceability.
B4: Business Intelligence and RM Tools	3	<ul style="list-style-type: none"> Describe the available reporting tools and or data management components of the solution. Given the rich repository of the tobacco tracing solution, identify opportunities for business intelligence and analysis tools that could support risk management efforts by EU Authorities. As a point of clarification, while sub-criterion A9 considers what existing oversight and monitoring functions are provided by the solution, sub-criterion B4 considers the reporting, business intelligence and data export tools themselves (which could be used for oversight purposes, but in addition, support other analysis and reporting objectives, e.g. collecting statistics for to support health policy related reporting).

Table 22 – Traceability Dimension: Functional Scope & Maturity

6.5.1 TRACEABILITY: BREADTH OF EXPERIENCE

The following table outlines what dimensions were assessed for each organisation, including how many current implementations they are operating, the experience they have in operating a system in general.

TRACEABILITY - DIMENSION: Breadth of Experience		
Sub-Criterion (Weight)	Description	
Criteria A. Current Implementations (Weighting: 3)		
A1: Proven Solution Components	2	<ul style="list-style-type: none"> The solution uses established technology components that are in existing operation today, not limited to the tobacco industry.
A2: Existing Fit for Tobacco Domain	2	<ul style="list-style-type: none"> The degree to which existing solution implementations fit the domain of tobacco as a regulated product with similarities to FMCGs.
A3: Implementation Experience (General)	2	<ul style="list-style-type: none"> Considers the implementation and project management capability of the service provider. Based on a scale using the number of implementations as a proxy indicator, with at least 5 implementations considered competent.

TRACEABILITY - DIMENSION: Breadth of Experience		
Sub-Criterion (Weight)	Description	
A4: Number of Sites	1	<ul style="list-style-type: none"> The total number of manufacturing and distribution sites that the solution has been implemented in globally. (An exponential scale was used assigning an increasing rating out of 10 for more than 1, 5, 25, 125 or 625 sites.)
A5: Number of Marked Items (per month)	1	<ul style="list-style-type: none"> This is simply a volumetric indicator of the total number of items marked and controlled by the solution (volume per month). Provides an indication of the size of current solution implementations being managed by the solution provider. (An exponential scale was used assigning an increasing rating out of 10 for more than 1.E+05, 1.E+06, 1.E+07, 1.E+08, 1.E+09 and 1.E+10 items marked per month)
A6: Holds Certifications and Standards	1	<ul style="list-style-type: none"> Evidence of standards and certifications currently held by the organisation.
B. Operations Experience (Weighting: 2)		
B1: Experience operating solution	3	<ul style="list-style-type: none"> The experience of the solution providers in terms of operating a traceability solution (whether proof of concept, pilot or commercial operation). While A4 considers the number of sites, this measure considers the nature of the implementation at those sites.
B2: Experience Providing Manufacturing Support / Maintenance	1	<ul style="list-style-type: none"> The operations experience of the organisation in terms of ability to provide support and maintenance to meet the demands of production lines within manufacturing facilities. Considers ability of solution provider to meet commercial objectives including offering a help desk and onsite support. While A4 considers the number of sites, this measure considers the nature the manufacturing support and maintenance provided to those sites.
B3: Experience as Equip. Provider	1	<ul style="list-style-type: none"> Conditionally applicable, it refers to the operations experience of the organisation as a provider of hardware or equipment provided to manufacturers and distribution chain operators.
B4: Experience as Software Provider	1	<ul style="list-style-type: none"> Conditionally applicable, it refers to the operations experience of the organisation as a provider of software and information technology applications to manufacturers, distribution chain operators, government and/ or consumers.
B5: Experience in Tobacco Domain	2	<ul style="list-style-type: none"> Operations experience of the solution provider in the tobacco domain.
C. Market Experience (Weighting: 1)		
C1: Breadth of Experience	1	<ul style="list-style-type: none"> Consideration for cross-learning benefits and opportunities to leverage experience the solution provider has obtained by operating solutions in other industries and across varied service offerings. Therefore, this sub-criterion endeavours to provide a proxy for a traceability that may be considered robust and flexible through implementations in multiple domains (e.g. fast moving consumer goods, food products, beverages), even if these do not yet include the tobacco domain.
C2: Years Organisation in Operation	1	<ul style="list-style-type: none"> A proxy for the maturity and experience of the organisation, and stability to weather business and economic cycles.

Table 23 – Traceability Dimension: Breadth of Experience

6.5.2 ORGANISATION SIZE (INDICATIVE)

The following factors were considered in rating the size of organisations. It should be noted that this has been included to provide an indication only, and that the assessment of these organisation characteristics do not affect their ratings on either the “Functional Scope & Maturity” or “Depth of Experience” dimensions.

Organisation Size	Description of Criteria
Organisation Turnover (€ millions)	Indicative value of Organisation financial turnover for the past 3 years.
Number of Employees	Total number of employees of the organisation
Num. Employees engaged in Solution	Indication of the number of employees that are involved in developing / providing track and trace and/or security feature related solutions.
Locations	Number of sites being operated by the solution provider

Table 24 - Indicative Organisation Size Criteria

6.6 SECURITY FEATURES EVALUATION CRITERIA AND SUB-CRITERION

The domain of security features is complicated by the vast variety of different participants involved in the industry, as well as the relationships and interdependencies established between those operators. Some of these operators have been active for several centuries, offering a broad menu of security feature options, whilst in some cases a specific security feature element is synonymous with the organisation itself, and requires closely guarded partnerships and alliances with other solution providers to supplement and create a more complete security feature product.

It is therefore not uncommon for security elements to be “mixed-and-matched” to develop a security package. Therefore, an analysis that focussed purely on the assessment of solution providers, would omit potential or emerging security feature technologies that potentially were not the purview of a solution provider. At the same time, regarding only the merits of a security feature technology, without consideration for the production, delivery and other operational aspects is also flawed. Therefore, to try and address these two considerations, the analysis for security features was conducted at two levels:

- An assessment of the solution providers themselves, using the a Assessment Matrix modified to include assessment criteria derived from the security feature critical success factors derived from the problem statement in Section 2; and
- An evaluation of the security feature technologies, using the subset of assessment criteria developed for the Security Feature Assessment Matrix, relevant to the technology itself.

In order to understand and rate each evaluation criteria effectively it was required to further distil each into sub-criterion. These criteria represented the level of detail against which each security solution provider was evaluated. The criteria and evaluation factors were prepared with reference to the Problem Statement and Security Feature Solution Critical Success Factors identified in Defining the Problem Statement in Section 2.4 above.

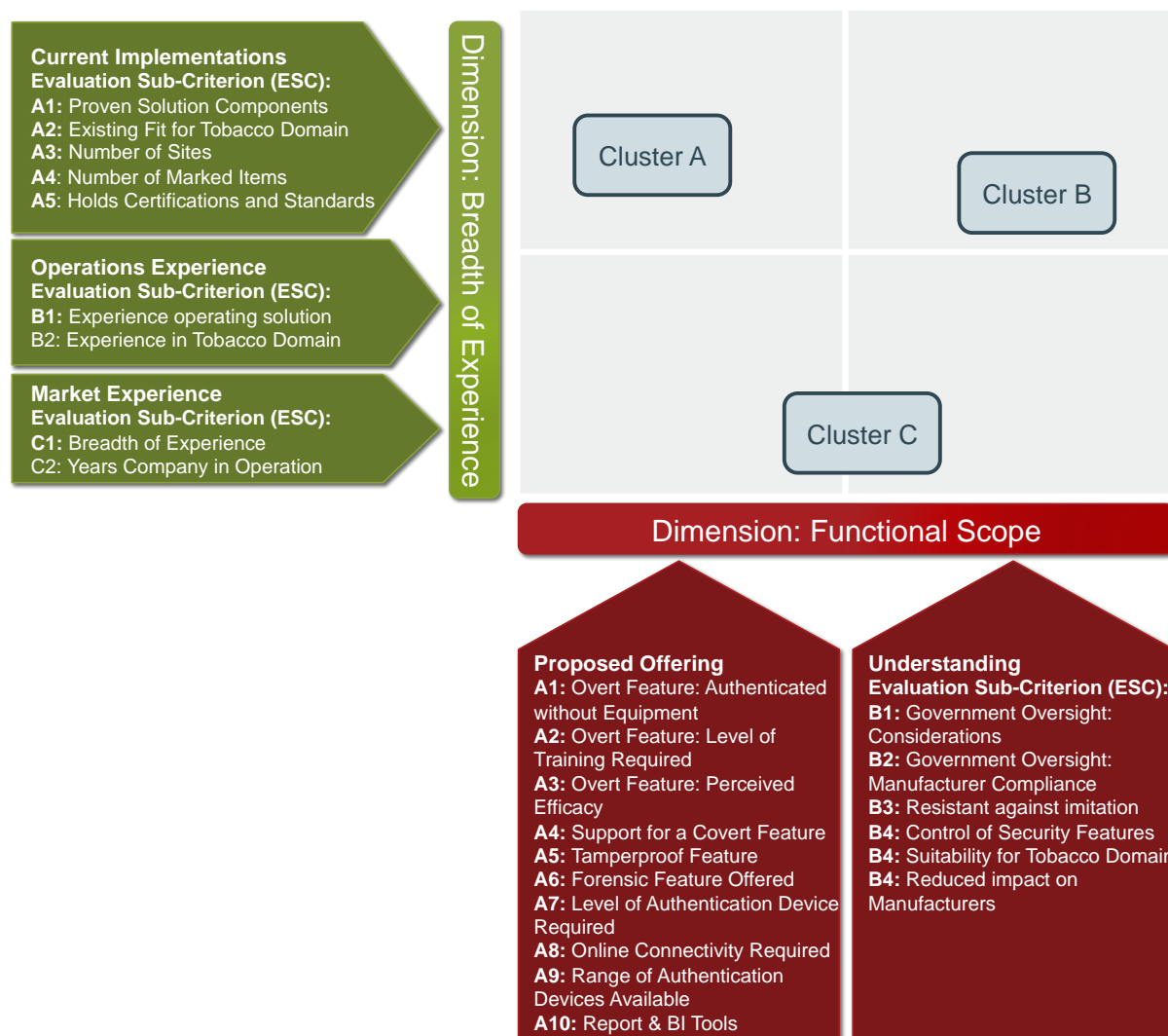


Figure 36 – Security Features Evaluation Sub-criterion

6.6.1 SECURITY FEATURES: FUNCTIONAL SCOPE & MATURITY

The functional scope & maturity axis consists of two primary dimensions: 1) The proposed offering of the solution provider, and 2) Level of understanding.

SECURITY FEATURE - DIMENSION: Functional Scope & Maturity		
Sub-Criterion (Weight)	Description	
Criteria: A. Proposed Offering (Weight: 2)		
A1: Overt Feature: Authenticated without Equipment	3	<ul style="list-style-type: none"> Does the overt feature meet the strict definition in terms of whether the cover feature can be authenticated without the support of an additional device or piece of equipment? Incorporated as such as a bridging mechanism to accommodate the requirements from TPD that specifies “visible”.
A2: Overt Feature: Level of Training Required	2	<ul style="list-style-type: none"> Perceived level of communication and training that would be required to understand the authentication process and interpret the authentication result. Considered from the perspective of consumers as the primary users of the overt / visible feature.

SECURITY FEATURE - DIMENSION: Functional Scope & Maturity		
Sub-Criterion (Weight)		Description
A3: Overt Feature: Perceived Efficacy	2	<ul style="list-style-type: none"> ▪ Consideration of how clear, verifiable and unambiguous the authentication result (from the perspective of the Consumer).
A4: Support for a Covert Feature	3	<ul style="list-style-type: none"> ▪ A check that the solution provider is able to offer a security feature that includes a covert (hidden) authentication element.
A5: Tamperproof Feature	3	<ul style="list-style-type: none"> ▪ Considers whether the solution provider offers elements to provide tamper resistance to the authentication feature.
A6: Forensic Feature Offered	3	<ul style="list-style-type: none"> ▪ Tests whether the solution provider recognises the need to add the third component of a security feature package that includes forensic to the security package.
A7: Level of Authentication Device Required	2	<ul style="list-style-type: none"> ▪ Considers the complexity and prevalence of devices that can be used to authenticate the covert security element. ▪ The EU problem statement and resulting functional requirements identifies several EU authorities that may be responsible for compliance monitoring and enforcement. The assumption is therefore that simple (e.g. a cheap polarising filter), common and multipurpose devices (e.g. smartphone) can increase reach and likelihood that the device will be on hand for field operations when required. ▪ Where the solution provider offers a range of authentication devices for multiple stakeholders, the best scoring devices rating is applied for this criterion.
A8: Online Connectivity Required	2	<ul style="list-style-type: none"> ▪ Evaluates whether an online connection (to the Internet) is required during the authentication process. ▪ The requirement for online connectivity can impose some restrictions on where items can be authenticated, and this limitation may be a consideration for enforcement operations or market surveillance teams.
A9: Range of Authentication Devices Available	1	<ul style="list-style-type: none"> ▪ Considers the extent the solution provider recognises the needs of different stakeholders (e.g. different use cases, affordability and degrees of authentication certainty), and is able to offer a range of authentication devices with different feature sets.
A10: Report & BI Tools	1	<ul style="list-style-type: none"> ▪ Description of the available reporting tools and or data management components of the solution.
Criteria: B. Understanding (Weighting: 3)		
B1: Government Oversight: Considerations	1½	<ul style="list-style-type: none"> ▪ Recognises the requirement for a tobacco control solution that offers functions to aid oversight of tobacco manufacturing operations for EU authorities and understands these resources are precious.
B2: Government Oversight: Manufacturer Compliance	1½	<ul style="list-style-type: none"> ▪ Support can extend to include reconciliation services and offering oversight of manufacturers to identify and alert anomalous events

SECURITY FEATURE - DIMENSION: Functional Scope & Maturity		
Sub-Criterion (Weight)		Description
B3: Resistant against imitation	3	<ul style="list-style-type: none"> An evaluation of the team of the plausibility and degree to which the security feature and authentication result can be imitated. Note: This criterion considers imitation, and not duplication or counterfeiting of the overt security feature. In other words, considers the extent to which the security feature can be imitated to the extent of falsely convincing a reasonable member of the public.
B4: Control of Security Features	3	<ul style="list-style-type: none"> The security feature solution provider should have an established process for order and secure delivery of the security feature materials to manufacturers.
B5: Suitability for Tobacco Domain	3	<ul style="list-style-type: none"> The security feature should be suitable for the tobacco domain, and its application compatible with tobacco packs and tobacco production processes. Security feature solution should accommodate manufacturers that may be located outside of the EU. Security feature should accommodate low-volume manufacturers (different degrees of automation).
B6: Reduced impact on Manufacturers	2	<ul style="list-style-type: none"> Solution takes into consideration minimising impact on tobacco manufacturers in terms of method for application of the security feature and integration with any tobacco packaging and production processes. While closely related with B5 above, going beyond compatibility with the tobacco domain, but reducing the impact of the security feature on the manufacturers operations. Further, consideration for minimising impact in terms of required supplies and equipment maintenance.

Table 25 – Security Feature Dimension: Functional Scope & Maturity

6.6.2 SECURITY FEATURES: BREADTH OF EXPERIENCE

SECURITY FEATURE - DIMENSION: Breadth of Experience		
Sub-Criterion (Weight)		Description
Criteria: A. Current Implementations (Weighting: 3)		
A1: Proven Solution Components	2	<ul style="list-style-type: none"> The solution uses established technology components that are in existing operation today, not limited to the tobacco industry.
A2: Existing Fit for Tobacco Domain	2	<ul style="list-style-type: none"> The degree to which existing solution implementations fit the domain of tobacco as a regulated product with similarities to FMCGs.
A3: Number of Sites	1	<ul style="list-style-type: none"> The total number of manufacturing and distribution sites that the solution has been implemented in globally. (An exponential scale was used assigning an increasing rating out of 10 for more than 1, 5, 25, 125 or 625 sites.)
A4: Number of Marked Items (per month)	1	<ul style="list-style-type: none"> This is simply a volumetric indicator of the total number of items marked and controlled by the solution (volume per month). Provides an indication of the size of current solution implementations being managed by the solution provider. (An exponential scale was used assigning an increasing rating out of 10 for more than 1.E+05, 1.E+06, 1.E+07, 1.E+08, 1.E+09 and 1.E+10 items marked per month)

SECURITY FEATURE - DIMENSION: Breadth of Experience		
Sub-Criterion (Weight)	Description	
A5: Holds Certifications and Standards	1	▪ Evidence of standards and certifications currently held by the organisation.
Criteria B. Operations Experience (Weighting: 2)		
B1: Experience operating solution	3	▪ The experience of the solution providers in terms of operating a traceability solution (whether proof of concept, pilot or commercial operation) and not limited to the tobacco industry.
B2: Experience in Tobacco Domain	2	▪ Operations experience of the solution provider in the tobacco domain.
Criteria: C. Market Experience (Weighting: 1)		
C1: Breadth of Experience	1	▪ Consideration for cross-learning benefits and opportunities to leverage experience the solution provider has obtained by operating solutions in other industries and across varied service offerings.
C2: Years Organisation in Operation	1	▪ A proxy for the maturity and experience of the organisation, and stability to weather business and economic cycles.

Table 26 – Security Feature Dimension: Breadth of Experience

6.6.3 ORGANISATION SIZE (INDICATIVE)

The following factors were considered in rating the size of organisations. It should be noted that this has been included to provide an indication only, and that the assessment of these organisation characteristics do not affect their ratings on either the “Functional Scope & Maturity” or “Depth of Experience” dimensions.

Organisation Size	Description of Criteria
Organisation Turnover (€ millions)	Indicative value of Organisation financial turnover for the past 3 years.
Number of Employees	Total number of employees of the organisation.
Num. Employees engaged in Solution	Indication of the number of employees that are involved in developing / providing track and trace and/or security feature related solutions.
Locations	Number of sites being operated by the solution provider.

Table 27 - Indicative Organisation Size Criteria

6.6.4 SECURITY FEATURE TECHNOLOGY ASSESSMENT

The evaluation of the security feature technologies is conducted as an analysis of the attributes and characteristics of the security feature that is agnostic of the organisation that is responsible for the development and supply of the security element. This analysis uses a subset of the sub-criteria that were developed for the Assessment Matrix assessment to evaluate each security feature.

For the assessment of the **overt** security element, the sub-criteria include:

- **Defence Against Imitation:** considers the extent to which the security feature can be mimicked or imitated to sufficient extent to falsely convince a reasonable member of the public. Note – this is distinct from replication which considers the extent to which the security feature can be reproduced to convince well trained and knowledgeable inspector, an assessment considered beyond the scope of this analysis.
- **Affordability:** Assessment of the price of the security feature, relatively to the other security features. A security feature with a high affordability rating it is cheaper to produce and apply than a security feature with a low rating.
- **Ease of Training:** Considers the level of training required to use the authentication feature, and interpret the result. A high rating indicates the security feature can be used with minimal training (general exposure and understanding of the feature and the authentication result), while a low rating indicates extensive training and knowledge required to authenticate the security feature.
- **Suitable for Tobacco Control:** Considers the extent to which the security feature is suitable for application, and authentication of tobacco products.

For the assessment of the **covert** security element, the same criteria as overt with the following additions:

- **Suitability for Enforcement:** Considers the use case of authentication the covert feature while in the field. High ratings were awarded where the authentication could be completed in typical mixed environments (e.g. retail, warehouse, border post), with a lower rating indicating less flexibility, as well as irreversible damage to the tobacco packaging that would adversely affect their sale after authentication.
- **Prevalence of Device:** Considers the complexity and prevalence of devices that can be used to authenticate the covert security element. Similar to the criteria used for the Assessment Matrix above, this requirement recognises that several EU authorities may require access to the covert authentication feature, with the assumption therefore that simpler devices improve the accessibility and usefulness for EU enforcement field operations. Therefore this scale rates simple unpowered devices (e.g. a cheap lens or filter) as most preferable, followed by common and multipurpose devices (e.g. smartphone) increasing to a proprietary device requiring proprietary consumables (e.g. chemical solution applied followed by scan using a device).

Evaluation ratings were considered and rationalised using research, experience and domain knowledge of the Team, supported by numerous security feature reports and industry reference materials⁹¹. Where relevant, survey response information was used to supplement these ratings, but generally responses were not sufficiently detailed at security element level.

The completed results are presented in a summary table using Harvey balls to visually represent the ratings for each criteria. To aid interpretation of the table, all criteria were worded and scales set to enable a standard interpretation, so that a higher rating always indicates the more desirable score for any particular criterion. As illustrated below, the results are presented using a summary table with Harvey Balls to aid visual interpretation.

⁹¹ Key references included: Institute of Research against Counterfeit Medicines, <http://www.iracm.com/en/table/>; SecuringIndustry.com <http://www.securindustry.com/about/s43/>; WHO Impact Assessment: <http://www.who.int/impact/events/IMPACT-ACTechnologiesv3LIS.pdf>;

Security Feature	Defence against Imitation	Affordability	Ease of Training	Suitable for Tobacco Control	Overall
Security Feature A					
Security Feature B					
Security Feature C					
Security Feature D					

Table 28 - Sample table illustrating presentation of Security Feature Assessment results

7 OVERVIEW OF MARKET SOLUTION LANDSCAPE

The following section provides a preliminary analysis of the current track and trace and security features market landscape based on the market survey assessment. As outlined in section 6 above, the modified Assessment Matrix allows the assessment weightings and scores to be adjusted based on reviewed priorities for each of the critical success factors, criteria and sub-criteria. It is proposed that these priorities be reviewed and agreed upon with members of the EU Commission project team before the Assessment Matrix results can be finalised. Therefore, the following is only a preliminary analysis and is therefore subject to change based on review and agreement of these parameters with the EU Commission team.

Further, note this preliminary analysis relies on the information provided by survey participants, the facts of which have been used as-is without confirmation, adjustment or adulteration.

7.1 PRELIMINARY TRACEABILITY ASSESSMENT MATRIX RESULTS AND KEY FINDINGS

The preliminary results show a wide spread of actors on the Assessment Matrix, both in terms of a functional scope & maturity, and depth of experience. Of the 42 organisations that completed the survey, a total of **32** indicated they provided a track and trace solution suitable for tobacco products. The sample included organisations offering security printing and security features, brand protection, track and trace control solutions (including providers specialising in control of regulated / taxed products) and organisations related to the tobacco industry itself.

With traceability only emerging as a control measure in the past several years, those organisations with the most experience in the domain have developed the more complete and considered solution offerings for control of a regulated product. Overall, there appears to be a general correlation between an organisation's depth of experience and the comprehensiveness of their solution offering. While this might indicate intra-correlation effects between the assessment criteria, in this solution domain for tobacco control it was somewhat expected.

Four organisations responded as providers of a track and trace solution that, in effect, was the same underlying track and trace solution being promoted by the tobacco industry under the umbrella of the Digital Coding and Tracking Association (DCTA). While the underlying technical solution is the same, there are some key differences in the solution offering and experience characteristics of each of these organisations'. As a result, there is some variation as to where these organisations are plotted on the Assessment Matrix.

The diagram below illustrates the four main categories of solutions identified during the Assessment Matrix analysis, and each of these groups are discussed further in the following section.

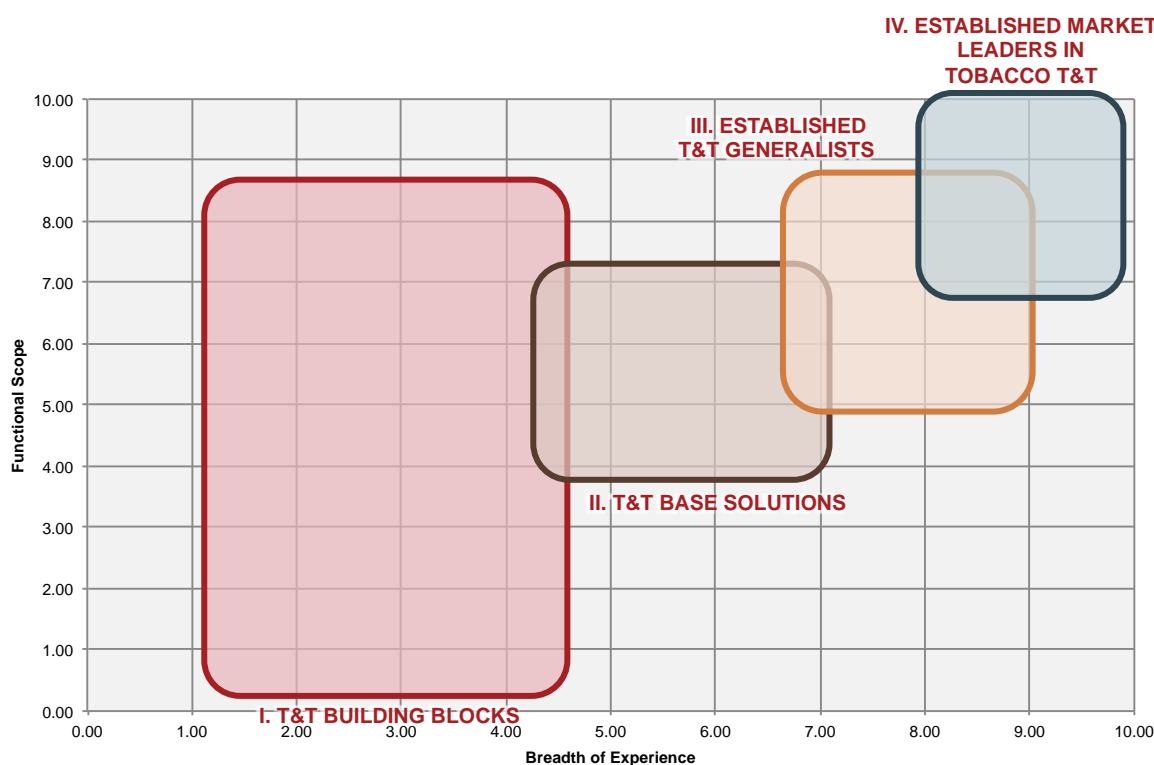


Figure 37 - Illustrative Solution Provider Typographies

7.1.1 GENERATION OF UNIQUE NUMBERS FOR TRACK AND TRACE

Since track and trace is a relatively new and emerging practice in supply chains (particularly with respect to item-level track and trace) there is a lot of marketing activity and hype in this area. As a result, it was not unexpected that a number of proposed track and trace solutions fail to consider several fundamental solution components beyond applying a unique number to a label or product. This group, scattered on the left half of the Assessment Matrix, is comprised largely of security printers and security feature technology providers that specialise or offer only a select number of basic components for a traceability solution (grouped as, "I. T&T Building Blocks" providers in Figure 37 above.)

Generally, these offerings are highly specialised on one specific component (e.g. security, a unique marking method or base fiscal markings only), and tend to have significant solution gaps, either because these elements are not required in their current industry domains or they rely on partnerships with other providers to develop a more comprehensive offering.

Specific solution gaps include, not recognising the hierarchy of tobacco packaging (aggregation) and not providing a feasible mechanism to integrate with the thousands of distribution chain operators that are required to provide tobacco-tracking information. The latter is especially important when recognising the commercial environment required for the TPD where distributors and wholesalers are dealing with thousands of products beyond just tobacco. For example, requiring these operators (which typically already have established warehouse and dispatch systems) to equip employees with a smartphone and proprietary application to specially record receipt and dispatch consignments that may contain tobacco products is neither feasible nor practical.

7.1.2 PROVIDING THE TRACEABILITY BASICS

There is a second clustering of track and trace solution providers on the Assessment Matrix that provide a basic offering for track and trace solutions (grouped as, "II. Track and Trace Base Solutions" in Figure 37 above). Although these providers demonstrate a developed, track and trace offering for a general brand protection strategy, they lack familiarity with the tobacco domain. There are some limitations and shortcomings in their offerings, specifically their suitability for the volumes and speeds associated with FMCGs, as well as the scalability of the required infrastructure to insure a cost-effective and reliable traceability solution.

7.1.3 PHARMACEUTICAL TRACEABILITY ENCOURAGES ESTABLISHED INDUSTRY GENERALISTS

Requirements stemming from pharmaceutical traceability legislation have been a significant contributor to the development of robust track and trace solution offerings. Developments in the pharmaceutical domain have outlined the requirements for a solid, reliable traceability solution operating beyond a single company, but reaching across an entire industry segment at national and even community levels.

Because of the scale, scope and value of this important industry segment, several of the established solution providers developed traceability solutions for serialisation and track and trace. Several of these pharmaceutical solution characteristics are shared with the requirements for a tobacco traceability solution, which results in a clustering of several of these established solution providers (grouped as, "Established T&T Generalists" in Figure 37 above.) This includes providers of production systems and equipment capable of supporting the scale and magnitude of the FMCG sector.

These competent traceability solutions tend to offer strong proposed offerings for serialisation (such as ensuring sparse, monotonic and non-predictable numbers) and the ability to handle aggregation and consideration of requirements for traceability beyond the manufacturer into the distribution chain (such as support for GS1 or EPCIS standards).

To create a typology stereotype, these solutions are somewhat generic with a focus largely on providing a mechanism for manufacturers to be compliant with the increasing number of traceability regulations being introduced for FMCG and pharmaceutical goods. Although competent traceability solutions, the majority of the solutions in this cluster were developed to expressly meet the requirements of the manufacturer, which are primarily concerned with the commercial objectives for brand protection or product recalls. As a result, most of the solutions in this third category provide only limited consideration and understanding of the requirements for a tobacco control solution with the objective of providing Governments with oversight of a regulated product and its distribution chain. Addressing these shortfalls to provide a solution with all required functions is likely to require further enhancement / development⁹².

The fourth cluster of solution providers do meet these additional oversight requirements and have established positions in track and trace of tobacco products (grouped as, Cluster IV in Figure 37 above.) Interestingly, one of these operators has achieved this through a pursuit to be a leading provider of oversight solutions for Government, while the other emerged out of an industry requirement to increase the level of control, offer brand protection and meet their obligations under tobacco anti-smuggling agreements with the EU.

⁹² See footnote 11 on page 18.

7.1.4 LIMITED EXPERIENCE IN OPERATING SOLUTIONS OF THE REQUIRED SCALE

The “Breadth of Experience” dimension includes several criteria establishing that the solution has actually been implemented, implementation experience has been gained and “teething” issues have been addressed. What is not immediately apparent in the Assessment Matrix is the vast difference in terms of the scale of the solution currently implemented by the two largest providers, as compared to the other experienced entities on the Assessment Matrix. To illustrate this disparity, the chart below shows the number of items per month controlled by the traceability solution, ranked from highest to lowest, with the largest two solution providers highlighted. Note, this table reflects items marked but does not take into consideration whether or not the marking is secure. For example, Solution Provider A uses secure marking techniques whereas Solution Provider B does not.

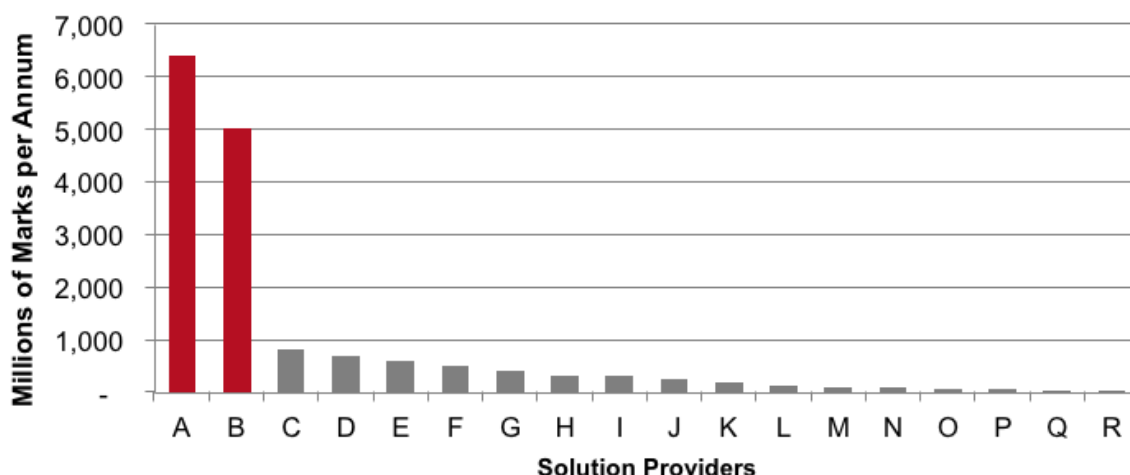


Figure 38 - Comparison of Number of Items Marked By the Solution Providers per Annum (where provided by survey participants)

Organisation A is significantly the largest operator in terms of the total number of items marked and recorded, with 6.5 billion items per month globally. Organisation B is comparable in size with some 5 billion items per month, worldwide. In contrast, the next largest operator currently marks and controls less than 20% of that volume. This disparity highlights the significant difference in scale to operate a solution for national authorities (as done by Organisation A and Organisation B), as compared to traceability solutions that may be offered commercially for specific organisations and / or products.

It is anticipated that this disparity between providers in terms of “scale” will change over the next 3 years with the entry in force of several serialization laws in the pharmaceutical sector. Solution providers in the pharmaceutical domain may be preparing for this, as they collectively will be required to simultaneously overcome the hurdles of operating solutions at this scale, and also address the requirements of a solution supported by infrastructures that are “provider agnostic”, where standards and interoperability will be key. Both organisation A and B have previously worked within a specific and focussed environment (either because it is their own industry or because the regional/national scope of implementation), with indications both organisations are actively pursuing opportunities to leverage their solutions and technologies within other industries, including pharmaceuticals.

7.2 PRELIMINARY SECURITY FEATURE ASSESSMENT MATRIX RESULTS AND KEY FINDINGS

The following section presents a comprehensive overview of security feature solutions. The analysis findings are presented in two parts:

- The overview of the security solution provider market using the Assessment Matrix, assessing performance against the assessment criteria and experience of those entities in operation; and
- The findings of the appraisal of security feature technologies themselves against the criteria established from the problem statement.

Please note this preliminary analysis relies on the information provided by survey participants, the facts of which have been used as-is without confirmation, adjustment or adulteration.

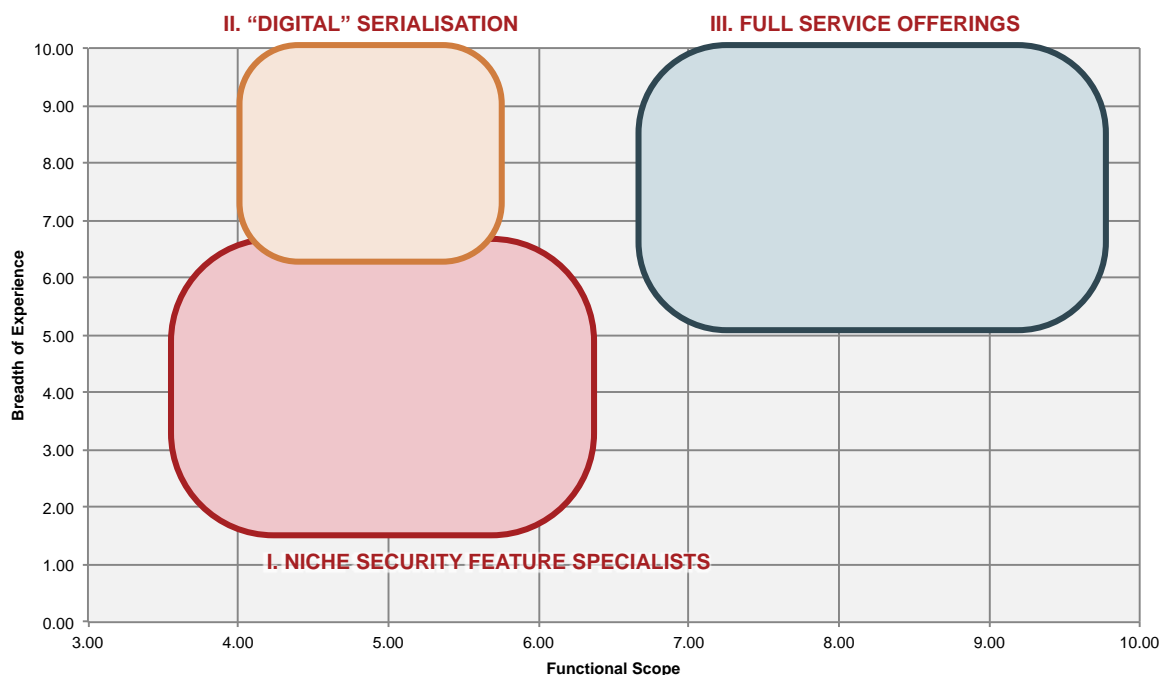
7.2.1 THE ASSESSMENT MATRIX FOR SECURITY SOLUTION PROVIDERS

Of the 42 organisation participating in the survey, a total of 37 organisations indicated they were a provider of security features suitable for tobacco products, and were included in the Security Feature Assessment Matrix analysis. This included a broad spectrum of security feature providers, including several established operators in this segment, a mix of new and emerging technology solution providers and organisations affiliated with the tobacco industry.

The preliminary mapping of the three main categories of security feature providers on the Assessment Matrix is presented in the figure below.

Four organisations responded as security solutions providers that used “digital” serialisation⁹³ that is the same underlying track and trace solution being promoted by the tobacco industry. All four of these organisations are promoting serialisation through the industry solution as a security feature, which is discussed further below.

⁹³ Serialisation is a concept where each and every item is marked with a unique identifier. This provides the basis to monitor and record the existence, location, and associated events of that item from the moment the mark is applied, potentially through its use / consumption lifecycle



7.2.1.1 NICHE SECURITY FEATURE PROVIDERS

A large cluster of security feature solution providers is in the bottom left quadrant, primarily providers that are specialised and offer only partial security feature offering (such as a forensic marker suitable as a covert element only).

This cluster also includes four organisations that provided weak responses or cited non-disclosure agreements in their survey responses. Unfortunately, the assessment criteria were applied to the provided responses and in these cases resulted in lower ratings.

7.2.1.2 DIGITAL SERIALISATION BEING OFFERED AS AN OVERT FEATURE

The top left of the quadrant contains a cluster of solutions that all share a common element. These solutions claim that an alphanumeric code applied to the tobacco packs provides an overt security feature to authenticate a tobacco product as authentic. These claims fall short, as the proposed serialisation technique fails to meet requirements of an overt security feature.

The overt security feature is intended primarily for consumer authentication and considers scenarios where authentication devices may not be on hand and time is limited. As cigarette products are most often kept behind the retail counter, a consumer has only a limited opportunity to use the authentication element and often under time pressure of other customers waiting in the check-out line. The authenticity of the tobacco pack cannot be determined by visually inspecting 12 alphanumeric codes printed on a cigarette pack. This provides a consumer with no visual indication as to the authenticity of the product.

At its best, code verification is a covert security feature, requiring either SMS or a Smartphone application to verify if the printed code is legitimate. This could confirm that the code itself is legitimate, but provides little assurance that it is simply not a valid code reproduced from a legitimate pack onto an illicit product. This duplication of the unique identifier fraud is identified in ISO16678: 2014(E), "Guidelines for interoperable objective identification and related authentication systems to deter counterfeiting and illicit trade"

(see "5.4.1 – Duplicate UID codes). To address these flaws, digital serialisation would need to be significantly augmented with additional security elements, including at least one overt feature, to provide a competent solution that meets the critical success factors of the Security Feature problem statement.

7.2.1.3 FULL SERVICE OFFERINGS

The analysis showed a strong cluster comprising more than 10 security feature solution providers in the top right quadrant. These organisations showed a competent understanding of security features with overt, covert and forensic elements. These organisations also demonstrated strong experience providing security features for use on currency, for brand protection purposes and on tax / fiscal markings.

Because there are so many providers in this quadrant, EU Member States should have little difficulty sourcing a capable provider for security features meeting the identified critical success factors suitable for tobacco products.

7.2.1.4 SECURITY FEATURE APPLIED RATHER THAN PRINTED ON PRODUCT

Survey responses showed there is a strong preference to apply security elements by **means of a label** to tobacco products. In fact, the label was put forward as the proposed application method by all respondents that offered both overt, covert and forensic security features (beyond serialisation). It is anticipated this is primarily because of the nature of the security feature industry and that a secure label allows:

- A far greater range of security elements and techniques to be used as the security feature provider has control over the substrate where additional security elements can be embedded (e.g. security fibres, taggants, nano-particles and/or RFID chips). These security elements would not be practical to apply directly on the tobacco packaging. This allows for a far greater range of security elements and techniques to be used;
- Production of the security feature to take place within a secure and controlled facility where access is restricted. This allows greater secrecy over production equipment and techniques to safeguard against the security feature package being compromised. This would be preferable to having the security features applied in uncontrolled commercial environments (e.g. commercial printers preparing tobacco packaging materials) or within the tobacco manufacturing facility itself; and
- A central controlled location where the techniques and security elements of the security feature can be adapted and upgraded over time to address evolving counterfeiting attempts and threats.

7.2.2 ASSESSMENT FINDINGS OF SECURITY FEATURE TECHNOLOGIES

The following section presents the analysis findings of the security technologies. The analysis considers the attributes and performance of the security feature technology and is therefore agnostic of any attributes or capabilities of the solution provider able to provide these security features.

7.2.2.1 OVERT SECURITY FEATURES

The table below presents the findings of the assessment of the overt security feature technologies. For a description of the criteria used, please see 0 above.

The analysis yielded the following preliminary findings:

- Colour shifting inks, various security printing techniques, foils and security threads were identified as a mix of competent security features. Colour shifting inks provided the highest defence against imitation amongst this category. The assessment of films showed defence against imitation varied considerably with more expensive films providing better security.
- Holograms provided a mixed overall performance. Whilst basic holograms are cheap to manufacture, they are very easy to imitate, creating a false sense of assurance. While highly sophisticated holograms (such as E-Beam from Holoflex) can contain security features that are almost impossible to copy, they are substantially more expensive and require extensive training for consumers and inspectors to authenticate. Because of this, basic holograms are not considered to provide efficient overt security, but can embed very strong and proprietary covert security features.
- Several security features that are effective for currency protection or brand protection were identified as not suitable for tobacco products. To be irremovable, it would require that the security feature be placed under the clear wrap on the cigarette pack, which would prevent tactile feedback (for authentication of intaglio printing) and light transmission effects (such as holding up to a light to verify watermarks or security films).

Table 29 - Summary of Overt Security Feature Technologies

Security Feature	Defence against Imitation	Affordability	Ease of Training	Suitable for Tobacco Control	Overall
Colour Shifting Inks	●	●	●	●	●
Printing: Guilloche	●	●	●	●	●
Printing: Microprinting	●	●	●	●	●
Security Threads and Fibres	●	●	●	●	●
Other OVD – Films	●	●	●	●	●
Iridescent ink	●	●	●	●	●
Metallic Inks	○	●	●	●	●
Hologram (datamatrix)	●	●	●	●	●
Holograms (EBeam)	●	○	○	●	●
Holograms (Stereogram)	●	●	●	●	●
Hot and Cold Foil Stamping	●	●	●	●	●
Watermarks	●	●	●	○	●
Holograms (2D/3D)	○	●	●	●	●
Printing: Intaglio	●	●	●	○	●

7.2.2.2 COVERT SECURITY FEATURES

The table below presents the findings of the assessment of the covert security feature technologies. The preliminary analysis yielded the following findings:

- The analysis shows a wide spread of security features ranging from highly affordable semi-covert features, requiring a simple device such as a coin to authenticate, through to forensic isotopic taggants, highly secure but neither particularly affordable nor particularly suitable in the context of tobacco control.
- A number of covert technologies were identified as unsuitable for field officials inspecting tobacco products where using the authentication required damage to

the tobacco packaging to access the security feature (e.g. coin reactive inks, thermochromic inks or chemical markers). Further, several required the addition of liquid substances to the security feature for authentication testing (e.g. DNA taggants), making these less suitable for field enforcement and better suited as forensic features for laboratory analysis.

- In terms of affordability, latent images and digital watermarks were identified as the most affordable (requiring only adaptation of digital print processes), whilst RFID chips were identified as the most expensive.

Table 30 - Summary of Covert Security Feature Technologies

Security Feature	Defense against Imitation	Affordability	Ease of Training	Suitability for Enforcement	Prevalence of Device	Overall
Latent Image	●	●	●	●	●	●
Digital Watermarks	●	●	●	●	●	●
Covert Symbolology (Pagemark)	●	●	●	●	●	●
Microparticles (e.g.Charms)	●	●	●	●	●	●
Metameric Ink	●	●	●	●	●	●
Cyrtoglyph (Type of Watermark)	●	●	●	●	●	●
Nanotext (Nanoimpression)	●	●	●	●	●	●
Hologram (Covert features)	●	●	●	●	●	●
Laser Taggants	●	●	●	●	●	●
Polarising Ink	●	●	●	●	●	●
Magnetic Ink	●	●	●	●	●	●
Tag Spheres	●	●	●	●	●	●
Serialised Hologram (Meditag)	●	●	●	●	●	●
Forensic Markers	●	●	●	●	○	●
Bi-Flourescent Ink	●	●	●	●	●	●
Infrared Ink (Anti-Stokes)	●	●	●	●	●	●
Nano Taggants	●	●	●	○	●	●
Chemical Markers (Spottag, Datag)	●	●	●	○	●	●
Flourescent Ink	●	●	●	●	●	●
Thermochromic Ink	●	●	●	○	●	●
Coin Reactive Ink	●	●	●	○	●	●
Photochromic Ink	●	●	●	●	●	●
RFID*	●	○	●	●	●	●
Conductive Ink	●	●	●	○	●	●
QR / Serial Codes	○	●	●	●	●	●
Isotopic Taggants	●	○	○	○	○	○

*RFID costs are generally considered prohibitive for pack level (approx 15x higher than other Security elements)

This wide range of covert features illustrates the possibility of selecting multiple features to build a security package that allows different features to be available to different stakeholders. For example:

- A latent image authenticated using a relatively affordable card filter could be provided to retailers or distribution chain operators as a means to authenticate products. This may be suitable for some Member States considering policies to hold retailers responsible if they are found dealing in illicit goods.
- A laser taggant could be included exclusively for use as an authentication method for EU officials as the means of verification of goods in the field.
- Forensic markers may be incorporated as random particles in the label substrate and only used for laboratory analysis for collecting evidence for case prosecution.

7.2.2.3 EMERGING FINGERPRINTING FEATURE TECHNOLOGIES

To complete the assessment, analysis was also performed on several fingerprinting technologies that rely on identifying and recording certain chaometric events that cannot be replicated. This emerging field offers several interesting developments for covert security features.

Three survey responses included security features that could be included in this category. All three of these technologies require an electronic device to complete the authentication, making them suitable as covert security features only. However, as some mitigation, two of those evaluated could be authenticated using a smartphone (together with a proprietary application), with the third utilising a smart phone equipped with a proprietary lens adaptor accessory.

An area of some concern in evaluation these emerging technologies is the issue as to whether these concepts will prove reliable and affordable operating at sufficient pace to support the high production speeds associated with the tobacco industry. It is therefore imperative that the ability of these technologies to operate under these conditions be validated during evaluation.

8 ASSESSMENT OF THE FOUR TRACEABILITY SOLUTION OPTIONS

The following objectives were considered during the development of the four proposed traceability solutions:

1. Identification of relevant considerations that may require further discussion and evaluation;
2. Meet the needs of multiple stakeholders (Health, Law Enforcement, Large and Small Manufacturers and Distribution Economic Operators);
3. Meet the requirements of the problem statement; and
4. Propose different governance models of traceability solution components between individual Member States and the EU (Community wide functions).

Several of the solution-critical success factors and requirements potentially conflict with one another, for example, mechanisms to create a solution that resists manipulation (critical success factor 10), may have additional impact on economic operators (critical success factor 8). Therefore, the following four options address a range of solution architectures, each attempting to provide an optimal compromise to balance different perspectives or stakeholder needs.

The following section outlines each of the four traceability options, provides a brief review of the key operational, technical and legal implications for each, and provides a summary of key considerations, advantages and disadvantages. It is recalled that the scope of the study does not provide a full legal assessment, but rather only a basic identification of legal requirements, without specifying exact legislative needs, impacts, affected acts and in particular, the partition of tasks between EU Member States and EU Commission.

8.1 ANALYSIS OF TRACEABILITY SOLUTION OPTIONS

One of the main goals of this report is to understand the implications of the four proposed traceability solution options on all stakeholders involved and understand the key advantages and disadvantages of each option. In the following sections the analysis outlines key implications across 3 main areas:

Operational Implications	➔	Examines the changes required to the operations of each stakeholder, including new business processes and capabilities.
Technical Implications	➔	Outlines the technical requirements the stakeholder will need to implement.
Legal Implications	➔	Provides a high level view of any anticipated legal or policy changes that will need to be implemented to support each solution option.

At each level, the report examines what is likely to be required from each of the following six primary stakeholders involved and how each may be affected:



The Options were assessed against the 11 critical success factors that are aligned to the Problem Statement as set out in section 2 above.

8.2 TOBACCO TRACEABILITY: OPTION 1

Option 1 is an industry-operated tobacco traceability solution; the EU Commission prescribes the standards but the tobacco manufacturers operate the solution (with the exception of the data storage, which is done by an independent Data Management Provider).

8.2.1 KEY PRINCIPLES

- EU Commission establishes the minimum data required on tobacco packaging and a mechanism for both EU and Member States authorities to have access to this data. The EU Commission prescribes standards and the format of how manufacturers and distribution chain operators submit tobacco information to independent data management providers.
- Tobacco industry is responsible for operating the tobacco traceability solution on their sites, making the required minimum data accessible to Member States and EU authorities. Generation, application and recording of the unique identifier on tobacco units, including aggregation and shipment events, is performed by the manufacturer using their own and/or industry-developed solution.
- Distribution chain operators record and submit tobacco tracking events either using their own systems (using EU prescribed form for data exchange) or using a solution / device provided by the tobacco manufacturers.
- Data storage is provided by 3rd party Data Management Providers (independent of manufacturers and distributors) with measures in place to guard against data losses or amendment by unauthorised parties.

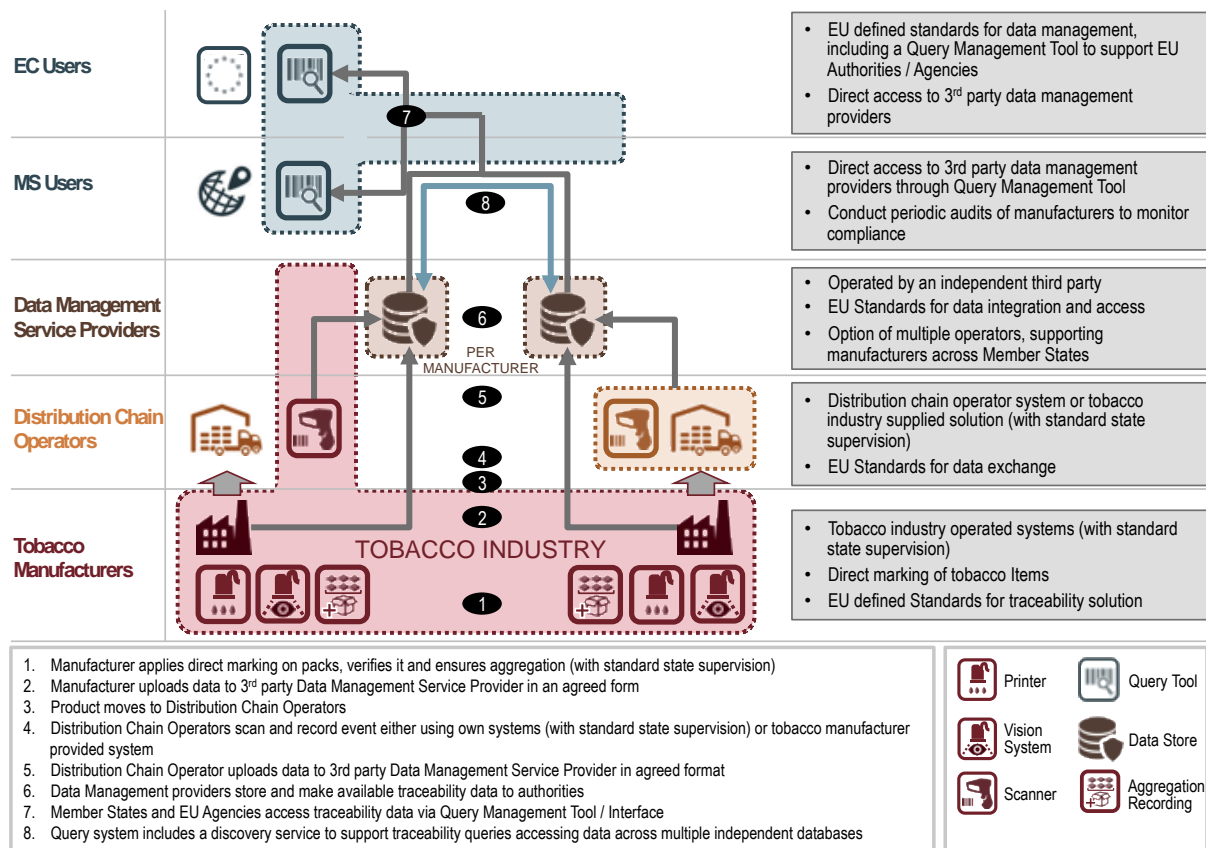


Figure 39 – Summary Overview of Solution Option 1

8.2.2 OVERVIEW

For solution Option 1 both Member States and the European Commission use an industry-operated solution for tobacco traceability. The European Commission defines requirements for information and method of marking of unit packets of tobacco, obligations for data recording and reporting, and minimum standards for interoperability. Solution Option 1 is generally consistent with the industries development and implementation of solution components, as promoted by the DCTA, with some adjustments perceived as necessary to fulfil the requirements as set out in the Problem Statement. Option 1 consists of the following:

- Tobacco manufacturers operate the serialisation process and select their own technologies for code generation, direct marking of tobacco units, secondary packaging marking, aggregation events and quality control.
- During the tobacco manufacturing process, traceability data is created and managed by Tobacco manufacturers.
- Compliance of tobacco manufacturers is assessed using current Member State supervision controls (e.g. periodic audit of tobacco manufacture processes as further described in Section 8.6.12 below).
- Distribution chain operators record logistic event updates as the tobacco products move through the distribution chain. These events are either recorded using their own information systems (where these systems are able to provide the required data using the prescribed interface standards for data submission), or by means of a solution provided by the tobacco manufacturers.
- The traceability data from manufacturers and distribution chain operators is provided directly to the 3rd party data management providers. The use of multiple

data repositories (potentially one per manufacturer) may necessitate the implementation of a discovery service responsible for routing tobacco tracking events to the relevant data repository.

- Member State agencies and EU authorities are able to access the tobacco traceability data directly from the 3rd party data repositories. EU enforcement agencies are able to use a smartphone application, provided by the tobacco industry, to read and decode pack markings and display available tobacco tracing information that may be accessed from the 3rd party data repositories when needed to support audits and investigations.

8.2.3 KEY IMPLICATIONS AND REQUIREMENTS

Note: Requirements that are very similar or identical to those that are common across all of the traceability options have been included in Grey to aid identification of the primary differences.

Stakeholder Option 1: Solution Requirements



Tobacco
Manufacturers

OPERATIONAL

- Tobacco Manufacturers (TMs) are responsible for sourcing and implementing equipment on each production line for coding (serialisation), aggregation, data collection and submission. Further, solution should include automated quality controls (such as vision system, or other validation system, to assess quality of unique identifier applied to tobacco units) business process quality controls (sampling) with associated rejection and exceptions management.
- TMs are responsible for maintenance and upkeep of tobacco traceability related equipment (whether self or in agreements with Original Equipment Manufacturers (OEMs) and required operation consumables.
- TMs are responsible for identifying an independent data management provider to provide a repository for tobacco traceability events for the manufacturers.
 - Propose data management provider to EU Commission for approval;
 - Operate bid and selection process; and
 - Contract management of service provider.
- TMs are required to maintain and provide the list of brands and products (SKU's) to the European Commission, Member States or Data Management Providers. This is especially relevant for items such as brand names or product descriptions that may be coded on packs and in electronic messages.
- TMs are required to register with an industry association, such as GS1 to obtain company specific prefixes:
 - Used by the manufacturer to generate serial codes applied to secondary packaging and provide the basis for these to remain unique throughout the distribution chain.
 - Assign a unique location number for each tobacco manufacturing facility and production line, such as the

Stakeholder Option 1: Solution Requirements



Tobacco
Manufacturers
- continued

GS1 Global Location Number (GLN) and GLN extension component (to accommodate each production line)⁹⁴.

- TMs must use packaging designs for unit packets of tobacco products that accommodate an area for application of the unique identifier:
 - For direct marking consideration of a suitable background colour (light areas suitable for inkjet and dark for laser), quiet zones, and varnish free with substrate suitable for marking type.
 - Location also requires consideration of accessibility for printing and readability during aggregation operations.
- TMs must use cartons and bundle packaging design that accommodates the application of a machine-readable and human readable serial code aligned to aggregation requirements.
- TMs must use quality control measures that include a rejection process for tobacco items where the unique identifier is absent or unreadable.
- For the generation of the unique identifier (containing data elements required in Article 15 §3) TM's will need to ensure additional data is made available to the coding system. The envisioned operational impact will further require either:
 - Operators setup and capture information onto the coding system as part of shift setup (e.g. Intended market of retail sale); or
 - Integration with the manufacturers' production systems for the required information to be received electronically by the coding system generating the unique identifiers.
 - As discussed further in 8.6.2 below, the requirement to include the intended shipment route as part of the unique identifier would have a substantive impact on current production scheduling, as currently the specific customer (and therefore upcoming warehouse locations for distribution to that customer) is in most cases not known at the time of manufacture (and therefore the application of the unique identifier to the unit packs of tobacco).
- TMs are required to adjust production lines in order to record aggregation operations and ensure the integrity of the parent-child relationships that are recorded.
 - For all cigarette manufacturers this would require pack-to-carton, carton-to-master case and master case-to-pallet aggregation, and the technical solution should support both automated and manual processes.
 - For other tobacco products this includes aggregation of the unit / pouch / tin-to-bundle, bundle-to-master case and

⁹⁴ Depending on requirements and format of data elements included as part of the unique identifier itself. Further, please see footnote 37 on page 48 above.

Stakeholder Option 1: Solution Requirements



Tobacco
Manufacturers
- continued

master case-to-pallet.

- **Note:** Manufacturers with existing agreements with the EU requiring master case and carton level tracking would already be operating solutions for several of these aggregation steps, and it is anticipated that this would only need to be extended to include pack-to-carton aggregation.
- TMs must modify dispatch operations to require the unique serial numbers⁹⁵ of the shipping items (at highest aggregation level) be recorded when shipments are staged and /or loaded.
 - Warehouse management system may record specific stock quantities per SKU; not necessarily by packaging identifier. Similarly, at the time of preparing an order, stock selection is likely to be based on required product type and first-in-first-out (FIFO) rather than selecting specific stock identifiers (which would require scanning of multiple items).
 - Therefore, only at the stage of order dispatched, can with certainty, the unique identifier of the pallet, master cases or carton be linked to the specific order number.
 - **Note:** These dispatch operations would already be performed to some degree by those manufacturers with agreements with the EU which requires the tracking of tobacco shipments to the 1st customer, whether currently at pallet or master case level. This operational impact would now become standard across all tobacco manufacturers.
- TMs will need to have on record information related to the next customer to which tobacco products are being dispatched, including both a reference number for the entity, and for the location to which the goods are being dispatched. These reference numbers would need to be unique for all operators across the EU. This might be managed using an industry organisation such as GS1 (including assigning unique references to all storage facilities by means of Global Local Numbers [GLN]).
- TMs are required to have exception processes in place to record damaged or unsellable goods (at various stages of aggregation) that already have unique identifiers assigned to them.
- TMs are required to have business processes to support the submission of commercial event data (invoice and payment records) to the 3rd party data management providers. The extent of commercial data required is considered specifically in 8.6.9 below.
- TMs must operate and maintain information and communications technology infrastructure that will be required at each manufacturing site linked to production line equipment.

⁹⁵ Unique serial number in this context refers to the unique identifier applied to secondary and tertiary packaging during aggregation processes.

Stakeholder Option 1: Solution Requirements


Tobacco
Manufacturers
- continued

- TMs outside of the EU manufacturing for the EU market will need to implement similar solution components as domestic manufacturers to conform to required tobacco product item marking, aggregation recording and traceability information event submission.
 - This may require a mechanism for the EU commission to review the tobacco traceability solutions that may be implemented in other non-EU countries, and the degree to which this meet the requirements for products placed onto the EU internal market;
 - Note: Countries outside the EU that intend to export tobacco products to the EU will have to comply with EU legislation. It is recognised that beyond this scope, EU traceability requirements cannot be imposed on manufacturers of tobacco product in countries outside the EU that do not intend to import to the EU. In the case these products are brought illegally onto the EU internal market, there remains the need for internationally agreed standards as a traceability minimum, by preference agreed under the FCTC protocol.
 - It is anticipated that tobacco manufacturers with multiple production facilities outside the EU may initially choose to minimise their investment in traceability solution components to certain facilities and consolidate tobacco manufacturing for the EU market to these facilities.
 - It is anticipated that marking of products on arrival in the EU territory would in most cases not be feasible for large volume products such as cigarettes:
 - Information such as production line, time and date is unlikely to be known.
 - The practicality of damage to the packaging that would be considerable to mark tobacco packs / items, parent packaging for the aggregation back to master cases is likely to be too costly.
 - For Other Tobacco Products (OTP), tobacco products other than cigarettes, with lower volumes and/or only finished in the EU, the application of the unique identifier and security feature may be practical after the time of import and before the products are placed onto the internal market.

TECHNICAL

- TMs may collaborate to develop shared solution components that implement EU Standards for unique identifier composition (e.g. Codentify), including elements to prevent duplicates and uniquely identify a manufacturer, facility and production line.
- To meet EU prescribed requirements for interoperability:
 - TMs apply a method (based on prescribed technical standards) for unique identifier generation, and the

Stakeholder Option 1: Solution Requirements


Tobacco
Manufacturers
- continued

encryption of the identifier for each pack that ensures the code applied to each pack is unique and the sequence is unpredictable.

- TMs use recognised industry standards for the machine-readable symbology / data carrier used for the unique identifier on tobacco items and serial identifiers on packaging (cartons, master cases and pallets). Standards agreed for EU to allow reading and decoding by downstream economic operators and EU and Member State authorities
- TMs ensure data transmission to 3rd party data management providers is in agreed form (e.g. GS1 EPCIS standard with agreed extensions to accommodate TPD Article 15 data elements).
- TMs are required to implement quality measures in terms of readability of the machine readable codes on tobacco items and packaging (compliance with the specification for the agreed symbology, as well as relevant quality measure standards, such as ISO/IEC15415:2011 Bar code print quality specification – two dimensional symbols, or related AIM DPM [used for data matrices] or equivalent)
- TMs must install and operate:
 - Equipment for marking of tobacco items with the unique identifier (recommended both machine readable and human readable)
 - Vision system, or other validation system, for quality control that mark is applied and associated rejection system.
 - Equipment to read the unique identifier applied to the items that are then packaged into a carton / bundle. Printing and application of a label containing a unique identifier for the carton / bundle.
 - Equipment to read the unique identifier applied to cartons / bundles that are grouped and placed in the master case. Printing and application of a label containing a unique identifier to the master case.
 - Equipment to read the unique identifier applied to master cases that are then palletized. Printing and application of a label containing a unique identifier to the pallet.
- TMs must ensure the integrity of aggregation events, aggregation stations for pack-to-carton and carton-to-master case should include physical and logic safeguards such as shields, covers, doors (including cabinet open / close sensors) to prevent potential interference or tampering (intentional or unintentional) that may affect the certainty of recording the correct “child” items with the associated “parent” container.
- TMs extensions to financial accounting systems will be required to create the link between the unique identifiers of the actual tobacco items with the associated commercial documents,

Stakeholder Option 1: Solution Requirements

Tobacco
Manufacturers
- continued

including invoice, order number, delivery notes and payment records:

- It is anticipated this will require a substantive enhancement of the ordering application to accommodate the recording of the unique identifiers of the pallets, master cases and/or cartons during the order picking process.
- Development of system interface for submission of this commercial event information to the 3rd party data management providers. It is anticipated that this specific requirement may have significant implications; these are discussed further in 8.6.9 below
- TMs infrastructure and network connectivity for collected and generated tobacco traceability events is to be uploaded to the 3rd party data management providers.
 - Secure transmission traceability information to 3rd party data management providers.
 - Secure temporary storage of production traceability data to accommodate temporary interruptions (offline) in connectivity.
 - Data of unique identifiers applied on packs is secured so that any theft of physical disks, unauthorised copying or interceptions of transmitted data does not compromise integrity of the traceability solution.

POTENTIAL LEGISLATIVE CONSIDERATIONS FOR EU AND MEMBER STATES IN RELATION TO MANUFACTURERS

- Legislation will need to reflect an obligation on TMs to provide information and keep records, and extend these where necessary, to support Member State tobacco supervision controls as they relate to the traceability solution:
 - Records on system operation including items marked, quality of markings and associated commercial information (e.g. order, picking lists and invoices).
 - Account for wastage and discrepancies.
 - Conduct and provide the results to Member State authorities of a regular internally conducted reconciliation between tobacco traceability information submitted, tobacco production and sales.
- Consideration of remedial measures, penalties, sanctions or potential legislative actions against manufacturers by EU and Member State authorities where non-compliance is identified.
- TMs follow a conformance process when implementing solution components for Member State / EU agency approval (operational readiness assessment).

Stakeholder Option 1: Solution Requirements**SME
Manufacturers**

In addition to the requirements identified above, the following are special considerations for Small and Medium Enterprise manufacturers (SMEs) that may have low levels of automation:

- SMEs with low production volumes undermine the business case to outfit the production lines with direct marking equipment. In this case, the unique identifier may be printed at the time of manufacture onto a label, which is then applied to the product.
 - Similarly, labels may also be suitable for the variety of packaging units associated with other tobacco products (e.g. hand-packaged cigars).
 - Specifications for the label can include delamination and/or frangible ⁹⁶ paper to increase difficulty of removing the label (in line with requirement for “irremovable”).
- SMEs with low levels of systemisation and / or use of consumer invoicing and accounting software with little opportunity for extension and customisation can operate an additional stand-alone system to meet tobacco traceability requirements.
 - This will have an operational impact of additional time required for the capture of information into traceability system.
 - Availability of such a stand-alone application meeting tobacco traceability requirements for serialisation, aggregation and shipping event notifications is uncertain in a dynamic environment. Development of a common SME tobacco manufacturer’s solution may be problematic as a result of intra-industry competition and undermine the possibility of shared development costs among the SME manufacturers themselves. However, developing requirements in the pharmaceutical traceability domain may introduce additional service providers of hosted (cloud based) traceability solutions suitable for SME’s.
- SMEs can use handheld devices capable of reading the machine-readable unique identifier on unit packets of tobacco to support manual aggregation processes, and the main operational impact envisaged is the additional time required to scan each item during packing operations.

**Distribution
Chain
Operators****OPERATIONAL**

- Distribution Chain Operators (DCOs) will be required to scan receipt of and dispatch of tobacco products.
- DCOs will need to have on record information related to the next customer to which tobacco products are being dispatched,

⁹⁶ Note: Delamination refers to a material that separates, comes apart when manipulated. Similarly, frangible papers come apart / disintegrate readily. These properties may provide an advantage to indicate attempts at tampering, removal or combat attempts to reuse a label.

Stakeholder Option 1: Solution Requirements


Distribution
Chain
Operators
- continued

including both a reference number for the entity, and for the location to which the goods are being dispatched. These reference numbers would need to be unique for all operators across the EU. This might be managed using an industry organisation such as GS1 (including assigning unique references to all storage facilities by means of Global Local Numbers [GLN]).

- DCOs will also be required to record unpacking / repacking operations to maintain the integrity of the aggregation hierarchy. For example, a distributor preparing a shipment may open a master case, remove cartons and re-fill it with different cartons to efficiently reuse the packaging. Each carton removed would need to be scanned to record and identify that it no longer is part of the master case, while each added item would similarly need to be scanned to record the association with the identifier of the master case. It is anticipated that this will be a new requirement and that scanning operations at this level are unlikely to be present in most current distribution chain operations today.
- DCOs will also be responsible for tracking the potential reuse of master cases for new shipments unrelated to the previous master case contents.
 - As identified above, to ensure integrity of the aggregation hierarchy, the items removed from the original master case would need to have been recorded as such, and the new contents each scanned if the original label and identifier were to be reused.
 - However, the preferable alternative would be that, in the case packaging is reused, any previous labels be removed and replaced with a new label specifying a new serial number, together with the relevant prefixes for that economic operator.
 - Similar to the above, an aggregation event would then be recorded to associate the new contents with the new master case identifier.
- The use of aggregation reduces the volume of scans required to receipt and dispatch items. It is anticipated that the majority of distribution chain operations will be recorded at master case level, at least during initial movements in the distribution chain. However increasing disaggregation is expected in approaching the last point before retail where mixing at carton level may be required to fill an order, with an increasing adverse operational productivity impact on the distributors as the number of lower items in the aggregation hierarchy need to be scanned and recorded.
- However, the operational impact of volume of items to be recorded is likely to be exacerbated for those distributors (and in some cases manufacturers in this role) operating a mobile direct sales force that may sell products to retailers with immediate order fulfilment.
 - It is anticipated that in most cases this will require disaggregating down to carton / bundle level. The

Stakeholder Option 1: Solution Requirements



Distribution Chain Operators - Continued

requirement to record the identifiers at this level, together with associated invoice data, will introduce significant operational impact and has been included in the proposed cost / benefit modelling in section 11 below.

- Further, while mobile handheld scanning devices within a distribution facility can be shared, each mobile sales representative will need to be equipped with a capable device or upgrade of existing devices for this purpose.
- DCOs maintaining vending machines will be impacted similarly, requiring events to be recorded at carton, and in some cases, individual pack / item level.
- DCOs are required to have processes in place to record traceability events for tobacco cartons and packs that may be returned - back to wholesaler, distributor and/or manufacturer- (reverse logistics).
- DCOs have requirements related to smaller distributors (with low levels of automation or basic warehouse management systems not capable of item level tracking):
 - Anticipated that smaller / less-automated distributors will utilise equipment provided by tobacco manufacturers for the scanning and recording the receipt, dispatch and logistic operations (disaggregation, re-aggregation).
 - Similar to large operators, SME distributors will need to register with an industry body such as GS1 to obtain prefixes to ensure facilities receive unique location identifiers and unique identifiers are applied to packages of aggregated tobacco product items.
 - By using a system independent of their existing distribution / warehouse systems for these operations, expectedly this will require users to re-capture data (such as supplier details during tobacco product receipt and customer details during tobacco product dispatch) with associated adverse productivity and process time impacts.
- It is interpreted that wholesalers selling to trade (retailers) only would not be considered the first point of retail, and will therefore need to meet reporting requirements in terms of the movement of tobacco products into and out of their possession, invoice, payment information and details of the purchaser, including for cash purchases typically associated with these operators.
 - **A substantial impact is anticipated where point of sale equipment generally is equipped for reading 1D barcodes, and not data matrices or ISS Dotcode considered for tobacco traceability marking of mastercases, cartons or packs:**
 - Whilst selling a wide variety of goods, any transactions involving tobacco products will be subject to these additional reporting requirements.
 - The identity of the purchaser at the time of sale will need to be recorded (even for cash transactions).

Stakeholder Option 1: Solution Requirements


Distribution
Chain
Operators
- Continued

- A mechanism will be required for recording both the GTIN / EAN barcode (to determine the stock item and system price to be charged), but also to scan the tobacco traceability identifier (SSCC or SGTIN) to identify the specific items being dispatched from stock.
- Point of Sale (POS) software will need to provide a mechanism to export the data of invoice, purchaser and specific tobacco items and system mechanism for this transaction data and be uploaded on a regular basis.

TECHNICAL

- DCOs will have the choice of using their own logistics and / or warehouse management systems (where this conforms to the agreed standards for information recorded and submitted in the prescribed form) or a simple system provided by the TMs.
- DCOs using their own systems to generate tobacco traceability events will need to enhance these systems to ensure that the identifiers of the highest level packaging item (e.g. pallets, master cases, cartons or even packs / tins / pouches) are recorded during receipt or dispatch operations.
- There is an option for highly automated DCOs to develop system interface for electronic submission of tobacco traceability events to 3rd party data management providers:
 - Industry standard interface standards such as GS1 EPCIS provide an existing interface specification for capturing events.
 - As option 1 considers a decentralised data repository (similar to options 3 and 4), connection to a discovery service would be required (potentially operated by tobacco manufacturers association) responsible for routing event notifications from the distributor to the relevant data repository.
- DCOs will use barcode readers capable of reading the machine-readable codes (carrier / symbology) used for pallets, master cases, cartons and units (packs / tins / pouches). The latter two items are important for preparing smaller shipments (where cartons may be repackaged into master cases) and handling reverse logistics (returns) that may be at pack level.
- DCOs distribution facilities will require a unique reference number assigned to the physical location and used when recording the location of goods received and origin of goods dispatched. To ensure this is unique across Member States (and globally), this master data should be managed. A unique number such as GS1 company prefix could be used in conjunction with a unique number assigned to each facility by the distributor to create a GLN.
- DCOs will use standards to ensure interoperability downstream of any labels or identifiers applied to secondary packaging materials, and ensures that these are unique (e.g. Distributor repacks a new master case containing a mix of tobacco product brands from

Stakeholder Option 1: Solution Requirements

Distribution
Chain
Operators
- Continued

different manufacturers, and applies a label containing a new unique identifier), such as GS1, which provides for a Serial Supply Chain Container Code (SSCC) and Serialized Global Trade Item Number (SGTIN) identifiers which can be encoded in either a 2D data matrix or GS1-128 barcode.

- To enable tracking of tobacco consignments at this level, it is anticipated that the majority of DCOs will be required to upgrade their warehouse management systems, packaging label printers and handheld reading devices.
- DCOs will require infrastructure and network connectivity for collected and generated tobacco traceability events that will be uploaded to the 3rd party data management providers (using EU agreed method for identifying relevant manufacturer data repository).
- DCOs will need to implement enhancements to accounting and financial systems to submit the related commercial information regarding invoices, order numbers, purchaser information and payment records.
 - It is anticipated that the extent of commercial data to be exported may have significant implications, these being discussed further in 8.6.9 below.

POTENTIAL LEGISLATIVE CONSIDERATIONS FOR EU AND MEMBER STATES IN RELATION TO DISTRIBUTION CHAIN OPERATORS

- DCOs are obligated to collect tobacco traceability information (receipts and dispatches), and to submit this information to the data management providers.
- DCOs must keep complete and accurate records of all tobacco product related transactions and need to be maintained for a prescribed period and provided as reference materials to support tobacco traceability queries in need.
- EU / Member State authorities assigned the responsibility of verifying compliance with the requirements for tobacco traceability have a legal basis to assess the compliance of DCOs, and therefore access distributor premises, request and audit tobacco traceability related information.
- Consideration of remedial measures, penalties, sanctions or potential legislative actions against distribution chain operators by EU and Member State authorities where non-compliance is identified.



Data
Management
Provider(s)

OPERATIONAL

- Data Management Providers (DMPs) offer data hosting services located in the Union in line with contracts concluded per tobacco manufacturer, and approved by the Commission.
- DMPs administer user rights and security access model to ensure

Stakeholder	Option 1: Solution Requirements
 <p data-bbox="199 353 375 481">Data Management Provider(s) - continued</p>	<p data-bbox="507 280 1324 347">information access to confidential information is available to authorised parties only.</p> <ul data-bbox="459 358 1380 616" style="list-style-type: none"> ▪ DMPs create a pilot / test environment for use by manufacturers to test system changes and enhancements. ▪ DMPs maintain audit logs that record access and activity related to all accounts. ▪ DMPs provide access to external auditors as necessary for their purpose to monitor activities related to the Data Management Providers. <p data-bbox="411 638 587 672">TECHNICAL</p> <ul data-bbox="459 694 1404 1400" style="list-style-type: none"> ▪ Routing and Discovery: DMPs include requirement for an EU-wide standard that enables the correct repository to be identified in order to determine the correct destination for a traceability event message. Further, for multiple data management providers it is recommended that a discovery service be implemented to route traceability events and queries to the appropriate event repository. ▪ DMPs implement support for industry standards for information exchange, such as EPCIS for traceability events, and Electronic Data Interchange (EDI) formats⁹⁷ for receiving of commercial documents (invoice, order, delivery note and payment records). ▪ DMPs provide a robust security model controlling parties that may update records, specifically with measures to prevent amendments and changes to existing records by tobacco manufacturers and distribution chain operators. ▪ DMPs provide an interface for authorised EU and Member State authorities to export tobacco traceability events to another repository for analysis ▪ DMPs implement secure data transmission and encryption techniques to be used for all received and transmitted data. <p data-bbox="411 1422 1276 1512">POTENTIAL LEGISLATIVE CONSIDERATIONS FOR EU AND MEMBER STATES IN RELATION TO DATA MANAGEMENT PROVIDERS</p> <ul data-bbox="459 1534 1404 1792" style="list-style-type: none"> ▪ DMPs adhere to data storage confidentiality requirements, duration of storage, tiered storage⁹⁸, access control, back-ups, business continuity and disaster recovery. ▪ DMPs agreements should include Service Level Agreements (SLAs) specifying availability and performance requirements. ▪ Standard service provider contract management considerations related to the data management provider(s)



Data Management Provider(s)
- continued

information access to confidential information is available to authorised parties only.

- DMPs create a pilot / test environment for use by manufacturers to test system changes and enhancements.
- DMPs maintain audit logs that record access and activity related to all accounts.
- DMPs provide access to external auditors as necessary for their purpose to monitor activities related to the Data Management Providers.

TECHNICAL

- Routing and Discovery: DMPs include requirement for an EU-wide standard that enables the correct repository to be identified in order to determine the correct destination for a traceability event message. Further, for multiple data management providers it is recommended that a discovery service be implemented to route traceability events and queries to the appropriate event repository.
- DMPs implement support for industry standards for information exchange, such as EPCIS for traceability events, and Electronic Data Interchange (EDI) formats⁹⁷ for receiving of commercial documents (invoice, order, delivery note and payment records).
- DMPs provide a robust security model controlling parties that may update records, specifically with measures to prevent amendments and changes to existing records by tobacco manufacturers and distribution chain operators.
- DMPs provide an interface for authorised EU and Member State authorities to export tobacco traceability events to another repository for analysis
- DMPs implement secure data transmission and encryption techniques to be used for all received and transmitted data.

POTENTIAL LEGISLATIVE CONSIDERATIONS FOR EU AND MEMBER STATES IN RELATION TO DATA MANAGEMENT PROVIDERS

- DMPs adhere to data storage confidentiality requirements, duration of storage, tiered storage⁹⁸, access control, back-ups, business continuity and disaster recovery.
- DMPs agreements should include Service Level Agreements (SLAs) specifying availability and performance requirements.
- Standard service provider contract management considerations related to the data management provider(s)

⁹⁷ EDI is electronic communication system for the exchange of business documents in a standard electronic format. Multiple standards exist including UN/EDIFACT (<http://www.unece.org/cefact.html>)

⁹⁸ Tiered storage assigns different categories of data to different types of storage media in order to reduce total storage cost. Categories may be based on levels of protection needed, performance requirements, frequency of use, and other considerations.

Stakeholder Option 1: Solution Requirements


Member State
Authorities

OPERATIONAL

- Requirement to extend the current Member States (MSs) supervision controls to include additional checks and balances for the purposes of validating integrity of a tobacco traceability solution:
 - The verification of the correct operation, implemented quality controls by the manufacture and the auditing traceability event histories for a sample of marked tobacco products drawn from the distribution chain.
 - Conduct random sampling of submitted tobacco traceability data events (both at manufacturers and distributors) including commissioned items, movements and commercial documents (orders, invoices and payment records).
 - Regularly conduct checks to reconcile tobacco traceability events with excise tax declarations and Customs declarations (e.g. transit).
 - Tally and compare volumes of security features used, with the volume of unique identifiers (or traceability commission events if used), as reported by the 3rd party data management providers.
 - Note: It is anticipated that, depending on the Member State, this could be included as part of an increased scope of the existing Excise audit function (where such audits in the tobacco sector occur regularly). This would have an associated operational impact on staff resources and capacity to perform the additional supervision controls related to the traceability solution such as those suggested above, to be applied.
- MSs conduct regular market surveillance campaigns to ensure tobacco items are correctly and legibly marked. These campaigns would also need to verify compliance of EU manufactured products and assess levels of illicit items on the internal market, if the traceability solution is to be effective to aid in detection of non-conformant tobacco products on the internal market
- MSs are given access to tobacco traceability data to support authorities' monitoring, reporting, surveillance and enforcement activities.
- MSs party to the WHO FCTC Protocol may wish to utilise access to tobacco traceability data for the purposes of responding to enquiries received through the global information-sharing focal point.
- Stakeholder education and consumer-awareness campaign activities related to introduction of tobacco traceability solution (and logically these activities may be combined with activities to promote consumer education of security feature).

Stakeholder Option 1: Solution Requirements


Member State
Authorities
- continued

TECHNICAL

- MSs should be able to access tobacco traceability data through either:
 - Query Tool provided by EU Commission; or
 - A technical interface for exporting tobacco traceability data to a Member State authority operated repository.
- MSs responsible for creating own tobacco distribution chain monitoring applications to use traceability data accessible from the 3rd party data management provider). Note: Tobacco tracing requests should not be routed via manufacturers systems.

POTENTIAL LEGISLATIVE IMPLICATIONS

- MSs provide approval and framework for regular review of tobacco manufacturer operated traceability solution components (recommend Member States institute a process for initial acceptance testing)⁹⁹.
- MSs agencies are required to provide authority and a legal basis to access tobacco manufacturer and distribution chain operator compliance. Will require legal basis to access premises, areas of tobacco production, storage facilities, information and request additional supporting documentation where required. This will be required for inspection of tobacco products under suspension of, or post-payment of any relevant duties and taxes. MSs have legal basis and sanctions to enforce technical standards for unique identifier composition, pack / item marking, secondary unit marking (e.g. carton), master case marking and pallet marking, together with aggregation events.
- MSs have access to distribution chain facilities for the purposes of assessing the compliance of these economic operators with tobacco traceability obligations.
- MSs consider a legal basis and sanctions to enforce technical standards for unique identifier composition, pack / item marking, secondary unit marking (e.g. carton), master case marking and pallet marking, together with aggregation events.
- MSs have legislative ability to enable submitted tobacco traceability data to be used by other national agencies / departments where a benefit of national interest can be demonstrated.

⁹⁹Consideration for co-operation between Member States should be considered, with possible considerations on currently available powers under Regulation (EU) No 389/2012 – Administrative cooperation in excise duties, and possibly Council Regulation (EC) No 515/97 – on mutual assistance between the administrative authorities of the Member States and cooperation between the latter and the Commission to ensure the correct application of the law on customs and agricultural matters

Stakeholder Option 1: Solution Requirements


EU Authorities

OPERATIONAL

- EU Authorities (EU) have access to tobacco traceability data using a query management tool developed and overseen by the European Commission, or through a interface provided to export traceability data. Both of these will be used to support relevant EU authorities to perform their responsibilities in terms of monitoring, reporting, surveillance and enforcement activities.
- EU facilitates joint Government and Industry working group to support and maintain specifications and standards. A critical function of the group during solution development implementation and post implementation is to provide a platform for tobacco manufacturers and distribution chain operators to resolve identified issues and track implementation progress.
- EU supports and maintains interoperability standards of tobacco traceability solutions implemented in Member States.
- EU conducts review of suitability of proposed data management providers nominated by the tobacco manufacturers for approval to operate a data storage repository for all relevant tobacco traceability data.
- EU reviews and approves the external auditors responsible for monitoring activities of the data management provider.

TECHNICAL

- EU prescribes minimum standards for interoperability in serialisation and data aggregation:
 - Pack Marking: Data elements, format and symbology / data carrier to be used for machine readable marking on tobacco packs (such as ISS Dotcode, GS1 data matrix) level of data redundancy (error correction), size and any required human readable elements.
 - Carton Marking: Data elements, format and symbology / data carrier to be used for machine readable marking applied to secondary packaging, including cartons in the case of cigarettes (such as ISS Dotcode, GS1 data matrix) level of data redundancy (error correction), size and any required human readable elements.
 - Use of existing industry standards for marking of master cases and pallets (e.g. GS1-128 barcode).
 - Principle that recording of aggregation relationships between packs and cartons, cartons and master cases and master cases and pallets should be definite / certain (i.e. not probabilistic).
- EU sets standards for interoperability of data exchange: form by which tobacco traceability data is submitted by tobacco manufacturers to the 3rd party data management providers:
 - Specification for data exchange that details the required data fields, format, interface and submission methods.

Stakeholder Option 1: Solution Requirements



EU Authorities
- continued

- Timing and frequency of data submissions (taking account of potential integration with movement control systems considered in 8.6.8 below).
- It is anticipated that existing GS1 EPCIS interface specifications could be used as the basis for submitting the required data on unique identifiers and the aggregation hierarchy relationships between the unit packets of tobacco products, secondary and tertiary packaging.
- European Commission oversees development and maintenance of a tobacco traceability query application that may be operated by EU and Member State authorities. The query tool will provide functions to:
 - Ensure authentication requests are authorized or allowed, that communication is authorized or allowed, and that the query is routed to the appropriate repository (query processing rule considerations under ISO16678:2014(E), Guidelines for interoperable object identification and related authentication systems to deter counterfeiting and illicit trade.
 - Trace the full event history for a particular tobacco item.
 - Validate the integrity of the recorded aggregation hierarchy.
 - View details for related items in a consignment, pallet, master case or carton / bundle.
 - A technical interface for exporting tobacco traceability data for analysis and reporting purposes
- **Note:** To ensure market surveillance, investigation and enforcement activities remain effective, traceability data requests should remain confidential to trusted parties only, and all tobacco traceability data requests, decryption and analysis should be processed independently of any tobacco manufacturing or distribution economic operator's systems.
- If required, the EU Authorities may designate a provider of additional applications to use traceability data accessible from the 3rd party data management provider.

POTENTIAL LEGISLATIVE IMPLICATIONS

- EU considers legal basis and sanctions to enforce technical standards for unique identifier composition, pack / item marking, secondary unit marking (e.g. carton), master case marking and pallet marking, together with aggregation events.
- Legal base for EU Authorities to access to tobacco traceability data to support relevant authorities to perform assigned monitoring, reporting, surveillance and enforcement responsibilities.
- EU considers legislation to enable submitted tobacco traceability data to be used by other national agencies / departments, where a benefit of national interest can be demonstrated.

Stakeholder Option 1: Solution Requirements

Consumers

It is not expected that there are any material implications resulting from Option 1 that will impact consumers.

8.2.4 KEY CONSIDERATIONS

- Member States and EU authorities should be able to decode the unique identifier and trace movement events independently. Tobacco traceability requests by Member States and EU authorities should be communicated directly, to the independent Data Management Provider. While such data access requests should be logged for governance and audit purposes, these logs should be stored and accessible to government authorities only. Therefore, there should be no indication to any other party, including tobacco manufacturers and distribution chain economic operators, of the time, location and nature of tobacco traceability requests that may otherwise compromise enforcement and investigation activities.
- Fraudulent manufacturers outside of the EU may be a risk if they attempt to manipulate the traceability solution. This could include reproducing codes from packs, cartons and master cases for additional production with the intention of escaping detection.
- Intellectual property ownership should be clear, with formal licensing agreements between any parties using such technology components to create an environment of stability and predictability for manufacturers and distribution chain operators investing in solutions to comply with the tobacco traceability requirements.
- To augment the traceability solution and offer a more holistic risk control model Distribution Chain Operators should receive messages regarding movement of their goods from point of origin to point of destination. This would create 'live' tracking environment of movements and enable a cumulative compliance model for the supply chain, where entities would be able to monitor the movement of goods and report on exceptions. To enable this function, DCO's would require the ability to send and receive messages from the traceability solution regarding their movements. The advantage of this functionality is pro-active triggering of exception events and encouraging self-regulating compliance of the distribution chain.
- A thorough analysis, including a security audit of the existing industry applications (code generator, line software, ERP systems etc.) for the creation of serialised marks was not in scope for this feasibility study. We have therefore not assessed the potential vulnerabilities (e.g., manipulation, storage and security of marks) for secure traceability along the end-to-end supply chain with respect to this application.

8.2.5 CONSIDERATIONS IN THE CONTEXT OF THE WHO FCTC PROTOCOL

The executive summary of a white paper released by the WHO FCTC Secretariat during COP 6 in October 2014, indicates a potential incompatibility of an industry-operated

solution with the WHO FCTC Protocol, and in particular its Article 8.2¹⁰⁰. A legal assessment of the compatibility of an industry operated solution with the WHO FCTC Protocol is beyond the scope of this project. It is therefore recommended that the EU Commission request a legislative and technical analysis of Option 1 and its compatibility to both the FCTC Protocol and Tobacco Products Directive.

8.2.6 KEY ADVANTAGES & DISADVANTAGES

Advantages	Disadvantages
<ul style="list-style-type: none"> ▪ Low administrative burden for the EU ▪ Low administrative burden for Member States. ▪ Competitive solution components costs ▪ Manufacturers have maximum flexibility and choice in terms of configuration and operation of production facilities . ▪ Lowest cost option for tobacco manufacturers. 	<ul style="list-style-type: none"> ▪ EU and Member state authorities reliant on tobacco industry as source of tobacco traceability data with dependence on existing Member State supervision mechanisms (e.g. excise audit) with expanded scope of monitoring compliance with tobacco traceability requirements. ▪ Reliance on tobacco industry to self-manage data integration and potential compatibility issues between economic parties. ▪ Risk is that the system might not provide reliable guarantees for independent control and management of the codes at pack level. ▪ Related to the above, it remains an open question whether the actual shared industry software components are free from vulnerabilities and functions that may compromise its integrity.

8.2.7 COMPATIBILITY WITH SOLUTION CRITICAL SUCCESS FACTORS

Presented below is a summary review of traceability Option 1 reconciled against the critical success factors identified as part of the problem statement.

1	Ensure each pack is marked with a unique identifier (Article 15, §1);	☑
2	Provide an accurate mechanism for recording the movement (tracking) of tobacco products through the point of manufacture to the last distributor before retail (Article 15, §5);	☑
3	Support the concept of aggregation (Article 15, §5);	☑
4	Store data independently (not by the tobacco industry) (Article 15, §8 and recital 31);	☑

¹⁰⁰ Extract from Conference of the Parties to WHO Framework Convention on Tobacco Control (6th Session), "Secretariat study of the basic requirements of the tracking and tracing regime to be established in accordance with Article 8 of the Protocol to Eliminate Illicit Trade in Tobacco Product, 17 October 2014": "*The tobacco industry actively promotes its own technology solution, Codentify, which it claims complies with the Protocol. However, based on desktop research, it appears that this system does not meet the requirement of Article 8.2 that the tracking and tracing system has to be "controlled by the Party".*

5	Ensure that the systems used for the unique identifier and the related functions are fully compatible with each other across the European Union (Article 15, §11b);	✔
6	Protect confidentiality and safeguard that decoding and full access to the data storage facilities is limited to authorised authorities and only exceptionally, in duly justified cases, to the tobacco industry, under restrictive conditions (Article 15, §8);	✔
7	As far as possible, be compatible with current tobacco production, packaging and the trade environment to minimise the impact on tobacco production, taking into consideration production speeds, equipment, etc. (internal market proportionality obligations);	✔
8	Uphold respect for data protection as specified in the EU legal framework (Directive 95/46/EC) (Article 15, §10);	✔
9	Be resistant to manipulation. This includes physical measures such as providing that marks are irremovable and indelible, but also solution design considerations such as non-predictability of unique identifier codes, traceability data reconciliation against other data sources, safeguards against traceability being accessed / used by unauthorised parties; (Article 15, §1)	⚠
10	Enable Member States and EU authorities to monitor and survey the market as per respective mandates (general aim of Article 15 and recital 29);	✔
11	As far as possible, used of solution components currently being used in a commercial supply chain environment and avoid unnecessary burden for business and/or authorities (Impact assessment considerations).	✔

Table 31 –Summary assessment of Traceability Option 1 Against Solution Critical Success Factors

Two explanatory comments are provided for the amber ratings for critical success factors 4 and 9 from the table above:

- Critical Success Factor item 4 requires that tobacco traceability data be stored independently (not by the tobacco manufacturers themselves): (a) This provides an assurance that the traceability data itself is stored in a manner that cannot be changed or adjusted outside of a controlled and auditable process; and (b) allows Member States and EU authorities to access the traceability data independent of any manufacturers’ systems or processes to prevent parties being alerted or having the possibility to interfere in possible investigations.
 - While it is the case with Option 1 that traceability data, including the unique identifiers and aggregation relationships between units, cartons / outers, mastercases and pallets, is submitted to the independent data management provider for storage, this data is also stored by the manufacturers (within the context of the current Codentify solution on the production line). Further, based on site visits to manufacturers, this is not done in a uniform manner, even though the same application for code assignment (Codentify) is being used for generation of the unique identifiers.
 - It is unclear if this *Modus Operandi* would support the intention of Article 15 §8 of the TPD, which specifies that only in duly justified cases should the tobacco industry have access to the stored data – as the tobacco manufacturers would have full access to their own copy of their traceability data.
 - This presents a number of potential risks, including that non-compliant manufacturers have the means to reproduce unique identifiers (as well as the corresponding aggregation relationships) onto undeclared tobacco products for diversion into the parallel illicit distribution chain; opportunity

to detect this risk may be minimal given the pragmatic reality that market surveillance may be limited resulting in a high statistical improbability that the duplicate codes would be detected. Instead, mitigation for this risk would more likely rely on state supervision controls of manufacturing activity (such as monitoring of raw material inputs) and potential volume controls associated with the security feature and / or tax stamp / fiscal marking programmes (where applicable).

- Further, in the scenario that unique identifiers from the tobacco products of compliant manufacturers are reproduced by counterfeiters onto illicit products and this is detected by law enforcement officials, a burden on the compliant manufacturer may unduly exist to explain their non-involvement, given the possible opportunity and potential motive.
- Critical Success Factor 9 indicates that the solution should be resistant to manipulation. A check mark has been assigned for this critical success factor for Option 1, but in amber, for the following reasons:
 - While the description of Codentify outlines a number of design features to secure the solution, it remains an open question whether the shared industry software components are free from vulnerabilities and functions that may compromise its integrity, and
 - Storage of the encrypted unique identifiers, together with aggregation information, by a tobacco manufacture, may potentially reduce the overall security of the solution (as raised in the commentary of critical success factor 4 above.

8.3 TOBACCO TRACEABILITY: OPTION 2

Option 2 involves the EU Commission prescribing the standards and appointing one or more solution providers to implement a community-wide tobacco traceability solution.

8.3.1 KEY PRINCIPLES

- A Single Tobacco Traceability solution deployed as a standard harmonised EU Community system; Member States enforce and ensure the solution is implemented by all tobacco manufacturers and distribution operators in their jurisdiction.
- The solution may be operated by one or more solution providers that are independent of the tobacco industry. The solution provider(s) implement technology components responsible for serialisation of tobacco items, recording aggregation events, and submission of traceability data to a single EU data repository for storing traceability event. EU Standards ensure interoperability of the solution components.
- EU Community system provides standard interface for distribution chain operators with automated systems to submit traceability data (receipts and dispatches) to the EU event repository. Alternatively, the provider(s) offer a stand-alone solution component for non-automated / SME distribution chain operators to record the receipt and dispatch of tobacco products, which is also uploaded to the central EU event repository.
- EU agencies and Member State authorities have access to a central EU event repository for monitoring and analysing tobacco traceability data. A further option for Member States may be the replication of this data to support national monitoring activities.

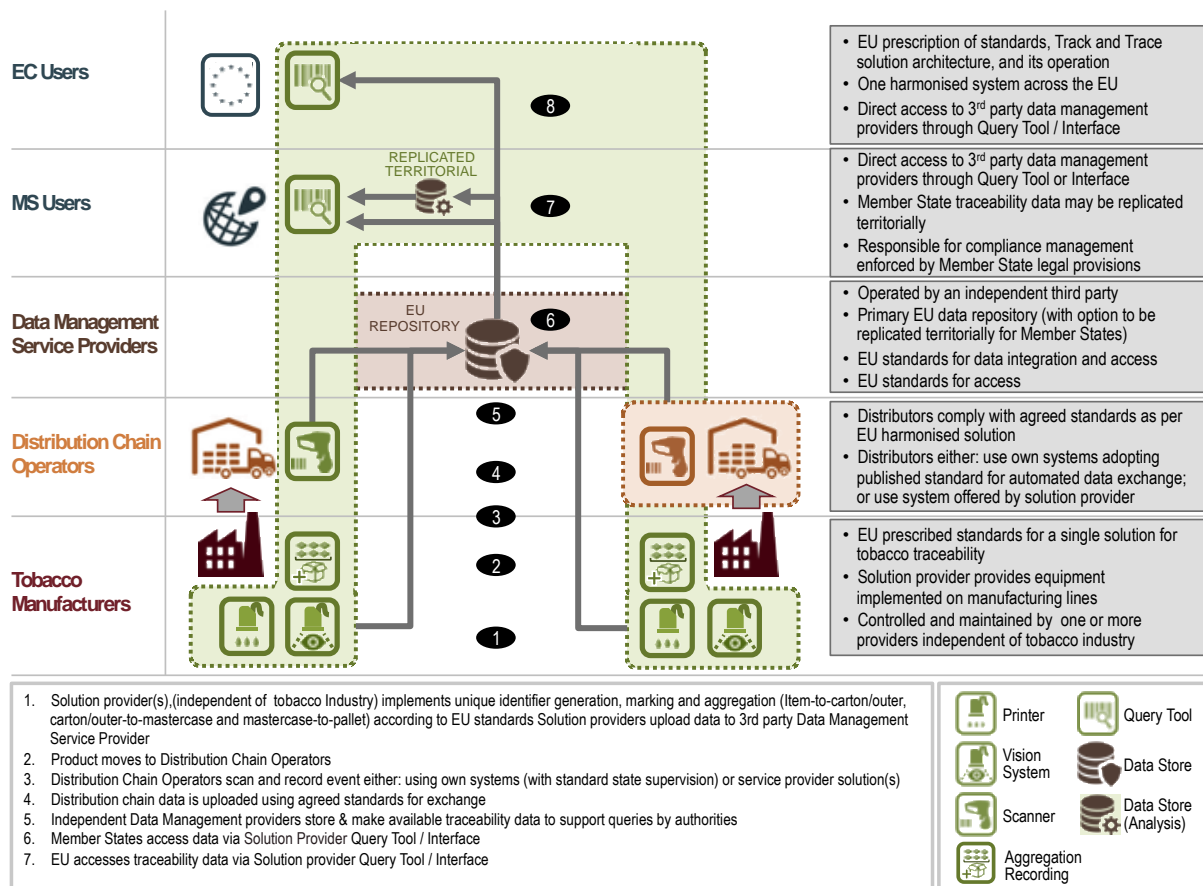


Figure 40 – Summary Overview of Solution Option 2

8.3.2 OVERVIEW

For Option 2, it is proposed that the EU Commission prescribes the standards and appoints one or more solution providers for the implementation of a community-wide tobacco traceability solution. The traceability solution standards are agreed upon across Member States and developed at the EU community level. Adoption by Member States is prescribed and compliance of manufacturers, importers and distribution chain operators is assessed through conformance testing and acceptance of components as a prerequisite for operation.

The tobacco manufacturers are required to allow the solution provider(s) to implement systems and equipment on their production lines prescribed by the EU for the serialisation of tobacco product at unit level, recording aggregation operations and identifiers of secondary and tertiary packaging and quality control. Direct marking is used as the default method for marking units of tobacco products at the time of manufacture with quality control mechanisms.

The traceability data is created and managed by the solution provider(s) of the EU-wide system. Distribution chain operators are required to record logistic event updates and submit these together with associated commercial information as tobacco products move through the distribution chain. This is achieved either by using their own systems that meet the required standard and submit this using an EU prescribed form, or by using a separate system provided by the solution provider(s).

Oversight by Member States and EU authorities is provided by the independent creation and application of traceability data at the time of manufacture, and through logistic events recorded by distribution chain operators using the EU-wide system. EU and

Member State enforcement agencies use traceability tools provided by the solution provider(s) to read and decode pack markings and access tobacco tracing information. Government authorities at both EU Community and Member State levels actively use all traceability data for monitoring and oversight purposes.

8.3.3 IMPLICATIONS

Note: Requirements that are very similar or identical to those identified previously and common across the traceability options have been included in Grey to aid identification of the primary differences.

Stakeholder Option 2: Solution Requirements



Tobacco
Manufacturers

OPERATIONAL

- Tobacco Manufacturers (TMs) are required to maintain and provide the list of brands and products (SKU's) to the European Commission and the Solution Provider(s).
- Each TMs location will require a unique location identifier. This requirement may either be accommodated by the Solution Provider(s) assigning unique codes to each facility and production line, or alternatively require the manufacturer to register with an industry association, such as GS1 to obtain prefixes and to assign a GS1 GLN and extension component for individual production lines.
- TMs must adapt packaging designs for unit packets of tobacco products to accommodate an area for application of the unique identifier.
- TMs cartons and bundle packaging designs must accommodate the application of a machine-readable and human readable serial code (aligned to aggregation requirements).
- TMs will need to make available information required for the generation of the unique identifier containing data elements required in Article 15 §3¹⁰¹. The envisioned operational impact will require either:
 - Solution provider(s) to provide a terminal / user interface for manufacturers operators to setup and capture information as part of shift setup (e.g. Intended market of retail sale); or
 - Provide an interface for manufacturers to provide messages from their production systems to receive the required information electronically for the coding operations.
 - Scanning of the retail barcode (EAN / GTIN) on the tobacco product unit as part of an automated solution operated by the solution provider(s) to reference required master data to determine the product description, intended market of retail sale.

¹⁰¹ See footnote 37 on page 48 above.

Stakeholder Option 2: Solution Requirements



Tobacco
Manufacturers
- continued

- Some potential issues with information available and feasible for encoding as part of the unique identifier are discussed further in section 8.6.2 below.
- TMs dispatch operations will require that the unique serial numbers of the shipping items (at highest aggregation level) be recorded when shipments are staged and /or loaded, with the same operational requirements identified as identified for Option 1.
 - An order number would need to be linked to the unique identifier of the pallet, master cases or cartons being prepared for shipping to be linked to the specific order number.
 - TMs will need to have on record the unique references numbers that identify customers and their storage facilities to which goods may be shipped (potentially using global supply chain standards such as GS1 GLN)
 - **Note:** These dispatch operations would already be performed to some degree by those manufacturers with agreements with the EU, requiring the tracking of tobacco shipments to the 1st customer, whether currently at pallet or master case level. This operational impact would now be standard across all tobacco manufacturers.
- TMs must have exception processes in place, with the Solution Provider(s) providing a system / mechanism for manufacturers to record damaged or unsellable goods (various stages of aggregation).
- As with Option 1, TMs will require business processes to support the submission of commercial event data (invoice and payment records) to the 3rd party data management providers.
 - It is envisaged that this may either be done electronically by the manufacturers accounting / financial systems using a system interface provided by the Solution Provider(s); or
 - By means of a capture system provided by the Solution Provider(s).
 - The extent of commercial data required is considered specifically in 8.6.9 below.
- TMs will need to accommodate within reason, representatives of the Solution Provider(s) being allowed access to production areas for the purposes of operation, maintenance and support of the tobacco traceability solution components.
- TMs may be requested to make available a space that can be secured and locked, suitable for the installation of server and communication equipment operated by the Solution Provider(s), as well as network connectivity from the allocated server room to the production lines.
- TMs must provide for network connectivity at each production site, for use by the Solution Provider(s) systems.
- TMs will advise Solution Provider(s) of maintenance schedules (to

Stakeholder Option 2: Solution Requirements



Tobacco
Manufacturers
- continued

optimise tobacco traceability solution maintenance times and minimise impact on manufacturers).

- Manufacturing facilities outside of the EU and manufacturing for the EU market will need to implement similar solution components as domestic manufacturers to conform to required tobacco product item marking, aggregation recording and traceability information event submission.
 - This may require a mechanism for the EU commission to review of the tobacco traceability solutions that may be implemented in other non-EU countries, and the degree to which these meet the traceability requirements for products placed onto the EU internal market;
 - **Note:** Countries outside the EU that intend to export tobacco products to the EU will have to comply with EU legislation. It is recognised that beyond this scope, EU traceability requirements cannot be imposed on manufacturers of tobacco product in countries outside the EU that do not intend to import to the EU. In the case these products are brought illegally onto the EU internal market, there remains the need for internationally agreed standards as a traceability minimum, by preference agreed under the FCTC protocol.
 - This may require the Solution Provider(s) to install and maintain the required equipment in these locations.
 - Requires a mechanism to assign these costs to / between tobacco manufacturers and to ensure off-shore production is of significant quantities to justify this capital costs.
 - As with Option 1, it is anticipated that marking of products on arrival in the EU territory would in most cases not be feasible for fully manufactured cigarette products, but may be feasible for low volume / specialised other tobacco products.

TECHNICAL

- TMs extensions to current financial accounting systems will be required to export commercial transaction information including invoice, order number, and payment records:
 - The Solution Provider(s) application will use this information to link the unique identifiers of the pallets, master cases and/or cartons during the order dispatch process.
 - It is anticipated that the extent of commercial data to be exported may have significant implications, and these are discussed further in 8.6.9 below.
- Depending on solution implementation method, TMs must provide a system interface to advise solution provider system of scheduled production information (e.g. intended market, product type).
- TMs must provide site network connectivity and power supply to

Stakeholder Option 2: Solution Requirements

Tobacco
Manufacturers
- continued

support Solution Provider(s) on-site equipment.

POTENTIAL LEGISLATIVE CONSIDERATIONS FOR EU AND MEMBER STATES IN RELATION TO MANUFACTURERS

- Legal basis required for fitment of tobacco traceability components on manufacturers' production lines.
- TMs are required to keep and record tobacco production, sale and movement data (for supporting verification and audit purposes).
- Policy in place for Member State / EU agency sign-off of manufacturers implementation (operational readiness assessment)
- Consideration of remedial measures, penalties, sanctions or potential legislative actions against manufacturers by EU and Member State authorities where non-compliance is identified.



SME
Manufacturers

In addition to the requirements identified above, the following are special considerations for SMEs that may have low levels of automation:

- SMEs with low production volumes or specific tobacco packaging requirements may impede use of direct marking methods for applying the unique identifier.
 - Therefore, the Solution Provider(s) may provide an alternative mechanism where the unique identifier is printed at the time of manufacture onto a label, which is then applied to the product.
 - Similarly, labels may also be suitable for the variety of packaging units associated with other tobacco products (e.g. hand-packaged cigars).
 - Specifications for the label can include delamination and / or frangible paper to increase difficulty of removing the label (in line with requirement for "irremovable").
- SMEs with low levels of systemisation and / or use of consumer invoicing and accounting software with little opportunity for extension and customisation may necessitate that the Solution Provider(s) provide a stand-alone system for the capture of information required for tobacco traceability purposes.
 - As with Option One, duplicate capturing activities will have an operational impact of additional time required for the capture of information into the traceability system.
- SMEs may choose to use handheld devices capable of reading the machine-readable unique identifier on unit packets of tobacco, and to support manual aggregation processes, where a further operational impact is envisaged in the additional time required to scan each item during packing operations.

Stakeholder Option 2: Solution Requirements



Solution
Provider

OPERATIONAL

- Solution Provider(s) (SPs) is / are responsible for sourcing and implementing equipment on each tobacco manufacturing production line for coding (serialisation), aggregation, data collection and submission. Further, the solution should include automated quality controls (such as vision systems to assess quality of unique identifier applied to tobacco units), and support for business process quality controls (sampling) with option to integrate with manufacturer's rejection system for unmarked or poorly marked tobacco packs to be rejected.
- SPs are responsible for maintenance and upkeep of their tobacco traceability-related equipment and required operation consumables.
- SPs provide support to tobacco manufacturers:
 - During implementation, conduct an assessment of each production line and develop a requirements document that outlines necessary preparations to be made by the manufacturer.
 - Support Manufacturers in complying with packaging design and line operations compatible with the tobacco traceability solution.
- SPs provide support to distribution chain operators:
 - Work with those distribution chain operators choosing to configure / enhance existing systems to electronically submit tobacco traceability events.
 - Provide distribution chain operators that do not have systems capable of submitting the required information with devices and equipment capable of recording the tobacco products received, purchased, sold, stored and transported. (**Note:** It is uncertain as to whether TPD Article 15 §7 would require a transfer payment from tobacco manufacturers collectively to cover these expenses).
- SPs should monitor and report on the tobacco items where the unique identifier is absent or unreadable and indicate if required EU prescribed service levels are achieved.
- Aggregation recording equipment on production lines should record necessary production operations and ensure the integrity of the parent-child relationships are recorded:
 - For all cigarette manufacturers this would require pack-to-carton, carton-to-master case and master case-to-pallet aggregation, and the technical solution should support both automated and manual processes.
 - For other tobacco products, this includes aggregation of the unit / pouch / tin-to-bundle, bundle-to-master case and master case-to-pallet.
- **Note:** Manufacturers with existing agreements with the EU,

Stakeholder Option 2: Solution Requirements

Solution
Provider
- continued

because of these agreements, may have needed to implement equipment for recording these aggregation steps, and in most cases this would need to be extended to include pack-to-carton aggregation.

- Because of this existing equipment, a consideration by the EU / Member States may be to require the solution provider(s) to conduct a review of existing equipment on tobacco production lines installed by manufacturers with such agreements and obligations to operate elements of a tobacco traceability solution (including direct coding printers, camera systems, aggregation recording equipment, label printers and applicators), and advise existing installed equipment that can be reused.
- A method may be prescribed to determine current market value (commercial or current manufacturer book value including applicable depreciation write-offs)
- Potential consideration for ownership of equipment eligible for re-use to be transferred to solution provider(s), with compensation to the manufacturer offset against their future payment contributions for operation of the tobacco traceability solution
- To minimise impact on manufacturers, a mechanism should be in place for SPs to monitor all operating sites to ensure tobacco traceability equipment is operating within acceptable parameters, receive alerts, and schedule any required and / or preventive maintenance.
- SPs provide support to EU and Member State authorities:
 - Provide query management tool and interface for authorised parties to access tobacco traceability data.
 - Assist with information requirements for audit, inspection and enforcement activities.

TECHNICAL

- SPs implement required serialisation components that meet EU Standards for unique identifier composition:
 - As several unique identifier generation and encryption algorithms contain proprietary technologies, it is proposed that the EU consider allocating a unique prefix to each Solution Provider, with the requirement that this be prepended to the generated unique identifier¹⁰².
 - Downstream there will be a requirement for interoperability in any mobile apps or query management tools.
 - As recommended above, that a prefix be prepended to specifically identify the SPs and ensure their code

¹⁰² For further consideration of ensuring identifiers for items are unique see ISO 15459 (1-8) -- Information technology — Unique identifiers

Stakeholder Option 2: Solution Requirements


Solution
Provider
- continued

generation process does not result in duplicates unique identifiers across the EU (and potentially globally too if this same standard approach is adopted elsewhere).

- SPs must meet EU prescribed requirements for interoperability:
 - Recognised industry standards for the machine-readable symbology / data carrier used for the unique identifier on tobacco items and serial identifiers on packaging (cartons, master cases and pallets). Standards agreed for EU to allow reading and decoding by downstream economic operators and EU and Member State authorities.
 - Data transmission to data management providers is in agreed form (e.g. GS1 EPCIS standard with agreed extensions to accommodate TPD Article 15 data elements).
- SPs are required to implement quality measure controls in terms of readability of the machine-readable codes on tobacco items and packaging (compliance with the specification for the agreed symbology, as well as relevant quality measure standards, such as ISO/IEC15415 or related AIM DPM [used for data matrices] or equivalent).
- SPs will ensure that all solution components and cabinets installed at manufacturers' and distributors' premises should be fitted with locks, sensors and seals and the ability to raise electronic alerts should there be any attempt to access equipment by unauthorised parties.
- SPs must provide an alternative solution for application of the unique identifier where direct marking may not be suitable, including small / low volume producers and / or producers of other tobacco products.
- SPs must provide complete solutions, including handheld scanners / reading devices for small manufacturers and distribution chain operators to record receipt, disaggregation, aggregation and dispatch tobacco events and associated unique identifiers.
- SPs provide, install and operate:
 - Equipment for marking of tobacco items with the unique identifier (recommended both a machine readable and human readable).
 - Vision system, or other validation system, for quality control that check that the mark is applied and signals associated rejection.
 - Equipment to read the unique identifier applied to the items that are then packaged into a carton / bundle. Printing and application of a label containing a unique identifier for the carton / bundle.
 - Equipment to read the unique identifier applied to cartons / bundles that are grouped and placed in the master case. Printing and application of a label containing a unique

Stakeholder Option 2: Solution Requirements


Solution
Provider
- continued

- o identifier to the master case.
 - o Equipment to read the unique identifier applied to master cases that are then palletized. Printing and application of a label containing a unique identifier to the pallet.
 - SPs should ensure the integrity of aggregation events, aggregation stations for pack-to-carton and carton-to-master case by including physical and logic safeguards, such as shields, covers, doors (including cabinet open / close sensors) to prevent potential interference or tampering (intentional or unintentional) that may affect the certainty of recording the correct “child” items with the associated “parent” container.
 - SPs operate servers at manufacturing site collecting data from production lines, system monitoring and reporting, and data upload to the central EU data repository.
 - o Secure transmission (encrypted and independent of tobacco manufacturers application systems) traceability information to data management providers
 - o Secure temporary storage of production traceability data to accommodate temporary interruptions (offline) in connectivity.
 - o Data of unique identifiers applied on packs is secured so that any theft of physical disks, unauthorised copying or interceptions of transmitted data does not compromise integrity of the traceability solution.
 - SPs develop and maintain a tobacco traceability query application that may be operated by EU and Member State authorities. The query tool will provide functions to:
 - o Ensure authentication requests are authorized or allowed, that communication is authorized or allowed, and that the query is routed to the appropriate repository (query processing rule considerations under ISO16678:2014(E), Guidelines for interoperable object identification and related authentication systems to deter counterfeiting and illicit trade.
 - o Trace the full event history for a particular tobacco item
 - o Validate the integrity of the recorded aggregation hierarchy
 - o View details for related items in a consignment, pallet, master case or carton / bundle.
 - SPs provide a system interface for EU and Member State authorities to access traceability data for analysis, as well as business intelligence, and reporting tools to provide oversight of the tobacco manufacture and distribution chain.
 - o Provide alerts for tobacco products located outside of intended markets
 - o Anomalous tobacco product storage at warehouse facilities (e.g. excessive time periods, indications that the volume of tobacco products at a particular location exceed the

Stakeholder Option 2: Solution Requirements

Solution
Provider
- continued

capacity of the facility, automated checking of value of goods vs. adequate bond / surety coverage and compliance reporting of entities in terms of receipt / dispatch reporting)

- Support / aid Member State authorities current state supervision controls
- Raise distribution chain exceptions (e.g. delays, deviations) (though this may warrant further consideration of the division of responsibility between the SP and authorities for alert, response and any subsequent follow-up activities).
- SPs have policy in place for Member State / EU agency sign-off of manufacturers implementation (operational readiness assessment)
- SPs provide information and record keeping requirements to support normal state supervision controls:
 - Records on system operation including items marked, quality of markings, and associated commercial information (e.g. order, picking lists and invoices)
 - Account for wastage and discrepancies
 - Conduct and provide the results to Member State authorities of a regular internally conducted reconciliation between tobacco traceability information submitted, tobacco production and sales.
- SPs adhere to strict confidentiality requirements to protect information on tobacco manufacturer's production, production capacity (planned or actual) with parties other than authorised EU and Member State authorities.

POTENTIAL LEGISLATIVE CONSIDERATIONS FOR EU AND MEMBER STATES IN RELATION TO SOLUTION PROVIDER(S)

- SPs adhere to information and record keeping requirements, including:
 - Records on system operation including items marked, quality of markings, aggregation events and received associated commercial information (e.g. orders, invoices and purchase records)
 - Regular information verification activities (including reconciliations) to ensure the tobacco traceability solution operates correctly.
- Standard service provider contract management considerations related to the solution provider(s)

Stakeholder Option 2: Solution Requirements



Distribution
Chain
Operators

OPERATIONAL

- Similar to Option One, the same implications will apply to Option Two in respect to Distribution Chain Operators (DCOs):
 - DCOs will be required to scan receipt and dispatch of tobacco products.
 - DCOs will need to have on record the unique references numbers that identify customers and their storage facilities to which goods may be shipped (potentially using global supply chain standards such as GS1 GLN)
 - A significant implication for DCOs will be the additional scanning required to maintain the integrity of the aggregation hierarchy to record unpacking / repacking operations
 - Restrictions on reuse and relabeling of packaging materials
 - It is anticipated that the majority of DCOs will be recorded at master case level during initial movements in the distribution chain with increasing disaggregation expected approaching the last point before retail where consignments may be disaggregated to **carton level**, and therefore scanned and tracked at this level.
 - Mechanisms in place to support reverse logistics events
- As with Option 1 a more substantial operational impact as a result of recording tobacco products at predominantly carton and pack level is expected for those DCOs operating direct sales force and servicing vending machines. These mobile teams will also require additional mobile devices for recording tobacco movements, sales and associated commercial information while in the field.
- Requirements related to SME DCOs (with low levels of automation or basic warehouse management systems not capable of item level tracking):
 - Anticipated that smaller / less-automated distributors will utilise equipment provided by solution provider(s) for the scanning and recording the receipt, dispatch and logistic operations (disaggregation, re-aggregation)
 - Similar to large operators, SME distributors will need to register with an industry body such as GS1 to obtain prefixes to ensure facilities receive unique location identifiers and unique identifiers are applied to packages of aggregated tobacco product items.
 - By using a system independent of their existing distribution / warehouse systems for these operations, it is expected this will require users to re-capture data (such as supplier details during tobacco product receipt and customer details during tobacco product dispatch) with associated adverse productivity and process time impacts.
- As with Option 1, a significant operational impact is foreseen for wholesalers selling to trade (retailers) that would need to upgrade

Stakeholder Option 2: Solution Requirements



Distribution
Chain
Operators
- Continued

their point of sale facilities to record the unique identifiers of tobacco products sold (over and above reading the current EAN barcode used for SKU identification), to record purchaser information and to submit this tobacco traceability event information.

TECHNICAL

- As with Option 1, DCOs will have the choice of using their own logistics and / or warehouse management systems (where this conforms to the agreed standards for information recorded and submitted in the prescribed form), or a simple system provided by the Solution Provider(s).
 - Operators using their own systems to generate tobacco traceability events will need to enhance these systems to record necessary identifiers from units / packaging during receipt or dispatch operations;
 - Support industry interface standards, such as GS1 EPCIS, which provide an existing interface specification for capturing events;
 - **Note:** Operation of a discovery service for routing event notifications from the distributor to the relevant data repository will not be required for Option 2 which proposes the use of a centralised EU repository.
- Similar to Option 1, DCOs will require barcode readers capable of reading the machine-readable codes (carrier / symbology) used for pallets, master cases, cartons and units (packs / tins / pouches). The latter two items are important for preparing smaller shipments (where cartons may be repackaged into master cases) and handling reverse logistics (returns) that may be at pack level.
- DCOs will be required to have a unique reference number assigned to the physical location, used when recording the location of goods received, and origin of goods dispatched. To ensure this is unique across Member States (and globally), this master data should be managed and maintained. While this could potentially be managed by the solution provider(s), it is recommended that the existing capability of an organisation such as GS1 be used (to also some extent future-proof and consider traceability requirements that may be considered on other food and health products in the future). A GS1 company prefix could then be used in conjunction with a unique number assigned to each facility by the distributor to create a GLN used in submission of EPCIS traceability events.
- DCOs will use industry standards to ensure interoperability downstream of any labels or identifiers applied to secondary packaging materials, and ensure that these are unique (e.g. Distributor repacks a new master case containing a mix of tobacco product brands from different manufacturers, and applies a label containing a new unique identifier), such as GS1 which provides for a Serial Supply Chain Container Code (SSCC) and Serialized Global Trade Item Number (SGTIN) identifiers which

Stakeholder Option 2: Solution Requirements

Distribution
Chain
Operators
- Continued

can be encoded in either a 2D data matrix or GS1-128 barcode.

- To enable tracking of tobacco products consignments at this level, it is anticipated that the majority of DCOs will be required to upgrade their warehouse management systems, packaging label printers and handheld reading devices where they choose not to use the Solution Provider(s) provided standalone solution.
- DCOs must provide Infrastructure and network connectivity for collected and generated tobacco traceability events to be uploaded to the 3rd party data management providers.
- DCOs will need to implement enhancements to accounting and financial systems to submit the related commercial information regarding invoices, order numbers, purchaser information and payment records.
 - It is anticipated that the extent of commercial data to be exported may have significant implications, these being discussed further in 8.6.9 below.

POTENTIAL LEGISLATIVE CONSIDERATIONS FOR EU AND MEMBER STATES IN RELATION TO DISTRIBUTION CHAIN OPERATORS

- DCOs are obligated to collect tobacco traceability information (receipts and dispatches), and to submit this information to the data management providers.
- DCOs must complete and maintain accurate records of all tobacco product- related transactions for a prescribed period, and if required, provide these records as reference materials to support tobacco traceability queries.
- EU / Member State authorities have legal basis to assess the compliance of DCOs, and therefore access distributor premises, request and audit tobacco traceability related information.
- Consideration of remedial measures, penalties, sanctions or potential legislative actions against distribution chain operators by EU and Member State authorities where non-compliance is identified.



Data
Management
Provider

OPERATIONAL

- Data Management Provider (DMP) provides data hosting service located in the Union in line with contracts approved by the EU Commission
- DMPs administer user rights and security access model to ensure information access to confidential information is available to authorised parties only
- DMPs create a pilot / test environment for use by Solution Provider(s) and distribution chain operators to test system changes and enhancements.
- DMPs maintain audit logs that record access and activity related to all accounts.



Stakeholder	Option 2: Solution Requirements
<p>Data Management Provider - continued</p>	<ul style="list-style-type: none"> ▪ DMPs provide access to external auditors as necessary for their purpose to monitor activities related to the Data Management Providers. <p>TECHNICAL</p> <ul style="list-style-type: none"> ▪ Differing from Option 1, 3 and 4, option 2 considers a single consolidated data management provider, and it is anticipated that a discovery service for the routing of tobacco traceability events and queries would not be necessary. ▪ DMPs must implement support for industry standards for information exchange, such as EPCIS for traceability events, and EDI formats for receiving of commercial documents (invoice, order and payment records). ▪ DMPs must provide a robust security model governing which parties may update records, specifically with restrictions to prevent amendments and changes to existing records by tobacco manufacturers and distribution chain operators. ▪ DMPs provide an interface for authorised EU and Member State authorities to export data on tobacco products traceability events to another database or repository for analysis. ▪ DMPs implement secure data transmission and encryption techniques to be used for all received and transmitted data. <p>POTENTIAL LEGISLATIVE CONSIDERATIONS FOR EU AND MEMBER STATES IN RELATION TO DATA MANAGEMENT PROVIDERS</p> <ul style="list-style-type: none"> ▪ DMPs adhere to data storage confidentiality requirements, duration of storage, tiered storage, access control, back-ups, business continuity and disaster recovery. ▪ DMP agreements should include SLAs specifying availability and performance requirements. ▪ Standard service provider contract management considerations related to the data management provider(s)
 <p>Member State Authorities</p>	<p>OPERATIONAL</p> <ul style="list-style-type: none"> ▪ Outputs of tobacco products traceability solution could be leveraged by Member States (MSs) agencies to support current supervision controls, as well as monitoring, reporting, surveillance and enforcement activities: <ul style="list-style-type: none"> ○ Provides independent verification of actual manufactured volumes – providing basis for automated reconciliation of excise duty liabilities. ○ Independent data provide data source to support risk-based control framework to optimise valuable resources expended on manufacturer site visits and audits. ▪ MSs would need to conduct regular market surveillance campaigns to verify compliance of EU manufactured products and

Stakeholder Option 2: Solution Requirements

Member State
Authorities
- continued

assess levels of illicit items on the internal market, if the traceability solution is to be effective to aid in detection of non-conformant tobacco products on the internal market

- MSs are given access to tobacco traceability data to support authorities' monitoring, reporting, surveillance and enforcement activities.
- MSs party to the WHO FCTC Protocol may wish to utilise access to tobacco traceability data for the purposes of responding to enquiries received through the global information-sharing focal point.
- Stakeholder education and consumer-awareness campaign activities related to introduction of tobacco traceability solution (and logically these activities may be combined with activities to promote consumer education of security feature).

TECHNICAL

- MSs are able to access tobacco traceability data through either:
 - Query Tool provided by Solution Provider(s); or
 - A technical interface provided by the data management provider for exporting tobacco traceability data to a Member State authority operated repository.
 - A business intelligence and reporting tool provided by the Solution Provider(s) to provide oversight of the tobacco manufacture and distribution chain, including alerts and reports to support / aid Member State authorities current supervision controls.

POTENTIAL LEGISLATIVE IMPLICATIONS

- Requirement for MSs be provided with authority and a legal basis to access tobacco manufacturer and distribution chain operator compliance. Will require legal basis to access premises, areas of tobacco production, storage facilities, information and request additional supporting documentation where required. This will be required for inspection of tobacco products under suspension of, or post-payment of, any relevant duties and taxes.
- Prohibit tampering, adjustment and movement of Solution Provider's equipment without prior notification and approval.
- MSs have access to distribution chain facilities for the purposes of assessing the compliance of these economic operators with tobacco traceability obligations.
- MSs consider a legal basis and sanctions to enforce technical standards for unique identifier composition, pack / item marking, secondary unit marking (e.g. carton), master case marking and pallet marking, together with aggregation events.
- MSs have legislative ability to enable submitted tobacco traceability data to be used by other national agencies / departments where a benefit of national interest can be demonstrated.

Stakeholder Option 2: Solution Requirements



EU Authorities

OPERATIONAL

- EU Authorities (EU) have access to tobacco traceability data using Solution Provider(s) tools, or through an interface provided to export traceability data. This data supports current EU authorities' monitoring, reporting, surveillance and enforcement activities.
- EU develops a review period and framework for conducting a basic audit of Solution Provider(s) activities:
 - Performance against Service Level Agreements (SLA's) and Key Performance Indicators (KPI) monitoring.
 - Audit of tobacco traceability information (sampling of items to validate recorded information) to validate integrity of solution.
- EU conducts review of suitability of proposed data management providers for approval to operate a data storage repository for all relevant tobacco traceability data for the EU-wide level.
 - Operation of bid and selection process.
 - Contract management of service provider for suggested considerations, see section 10 below.
- EU reviews and approves the external auditors responsible for monitoring activities of the data management provider.

TECHNICAL

- EU prescribes minimum standards for interoperability in serialisation and data aggregation:
 - Pack Marking: Data elements, format and symbology / data carrier to be used for machine readable marking on tobacco packs (such as ISS Dotcode, GS1 data matrix) level of data redundancy (error correction), size and any required human readable elements
 - Carton Marking: Data elements, format and symbology / data carrier to be used for machine readable marking applied to secondary packaging, including cartons in the case of cigarettes (such as ISS Dotcode, GS1 data matrix) level of data redundancy (error correction), size and any required human readable elements.
 - Use of existing industry standards for marking of master cases and pallets (e.g. GS1-128 barcode)
 - Principle that recording of aggregation relationships between packs and cartons, cartons and master cases and master cases and pallets should be definite / certain (i.e. not probabilistic).
- EU sets standards for interoperability of data exchange: Form by which tobacco traceability data is submitted by the solution provider(s) to the data management providers:
 - Specification for data exchange that details the required data fields, format, interface and submission methods.

Stakeholder	Option 2: Solution Requirements
 <p data-bbox="188 376 384 436">EU Authorities - continued</p>	<ul style="list-style-type: none"> ○ Timing and frequency of data submissions (taking account of potential integration with movement control systems considered 8.6.8 below in below). ○ It is anticipated that existing GS1 EPCIS interface specifications could be used as the basis for submitting the required data on unique identifiers and the aggregation hierarchy relationships between the unit packets of tobacco products, secondary and tertiary packaging. <ul style="list-style-type: none"> ▪ Similar to the Member State authorities, EU Authorities will be able to access tobacco traceability data through either a Query Tool provided by Solution Provider(s); a technical interface for exporting tobacco traceability data to an EU authority operated data repository or a business intelligence and reporting tool provided by the solution provider(s). ▪ If required, the EU Authorities may designate a provider of additional applications to use traceability data accessible from the 3rd party data management provider. <p>POTENTIAL LEGISLATIVE IMPLICATIONS</p> <ul style="list-style-type: none"> ▪ EU considers legal basis and sanctions to enforce technical standards for unique identifier composition, pack / item marking, secondary unit marking (e.g. carton), master case marking and pallet marking, together with aggregation events. ▪ Legal base for EU Authorities to access to tobacco traceability data to support relevant authorities to perform assigned monitoring, reporting, surveillance and enforcement responsibilities. ▪ EU considers legislation to enable submitted tobacco traceability data to be used by other national agencies / departments where a benefit of national interest can be demonstrated. ▪ EU requires legal basis for solution provider(s) to request access to manufacturers' premises, install and maintain equipment on production lines and be provided access to power and network connectivity.
 <p data-bbox="209 1641 363 1664">Consumers</p>	<p data-bbox="411 1563 1409 1624">It is not expected that there are any material implications resulting from Option 1 that will impact consumers.</p>

8.3.4 KEY CONSIDERATIONS

- An analysis, including a security audit of existing solution provider applications (code generator, line software, ERP systems etc.) for the creation and recording of serialised marks was not in scope for this feasibility study. While general mechanisms should be implemented to ensure the correct operation of the traceability solution, the scope for a largely automated control may include the reconciliation of summary traceability data created and recorded by the independent solution provider [and stored by the data management provider(s)]

against the declarations for excise tax purposes made by the tobacco manufacturers. Further, reconciliation with an additional data source may include the volumes of security feature elements used, and where in operation in a member state, the volumes of tax stamps used.

- In terms of software quality, it is anticipated that a competitive bidding environment for the selection of the provider(s) creates an economic and reputational interest for the provider to ensure that their solution is free from defects and vulnerabilities that may compromise its integrity. Such reputational considerations would be dependent on the particularities in the design of a bidding (such as frequency of repetition)
- In order to comply with their obligations under the TPD, Tobacco Manufactures will have to pay for both the implementation and operation of the traceability solution. The implementation and operation of this payment mechanism was outside the scope of this report.

8.3.5 CONSIDERATIONS IN THE CONTEXT OF THE WHO FCTC PROTOCOL

It is anticipated that Option 2 could be implemented in a manner compatible with the Protocol.

8.3.6 KEY ADVANTAGES AND DISADVANTAGES

Advantages	Disadvantages
<ul style="list-style-type: none"> ▪ Full EU Government and Member State oversight of tobacco traceability solution (from manufacturer through distribution chain). ▪ Segregation of tobacco traceability recording and tobacco production for industry mitigates risk of collusion. ▪ Economies of scale advantages for solution components. ▪ Consolidation of data storage to a single location simplifies administration, maximises performance (e.g. query response time) and facilitates cross Member State analyses. ▪ Standard tobacco traceability solution across all EU Member States. ▪ Standards for interoperability create an option to nominate more than one solution provider and create opportunity for competitive bidding, innovation, service and price. 	<ul style="list-style-type: none"> ▪ Prescribed solution components reduce flexibility for manufacturers and requires reassessment of made investments and existing solutions. ▪ Risk mitigation required to prevent traceability solution components causing production down-time.

8.3.7 COMPATABILITY WITH SOLUTION CRITICAL SUCCESS FACTORS

A summary review of traceability option 2 against the critical success factors identified as part of the problem statement is presented below.

1	Ensure each pack is marked with a unique identifier (Article 15, §1);	☑
2	Provide an accurate mechanism for recording the movement (tracking) of tobacco products through the point of manufacture to the last distributor before retail (Article 15, §5);	☑
3	Support the concept of aggregation (Article 15, §5);	☑
4	Store data independently (not by the tobacco industry) (Article 15, §8 and recital 31);	☑
5	Ensure that the systems used for the unique identifier and the related functions are fully compatible with each other across the European Union (Article 15, §11b);	☑
6	Protect confidentiality and safeguard that decoding and full access to the data storage facilities is limited to authorised authorities and only exceptionally, in duly justified cases, to the tobacco industry, under restrictive conditions (Article 15, §8);	☑
7	As far as possible, be compatible with current tobacco production, packaging and the trade environment to minimise the impact on tobacco production, taking into consideration production speeds, equipment, etc. (internal market proportionality obligations);	☑
8	Uphold respect for data protection as specified in the EU legal framework (Directive 95/46/EC) (Article 15, §10);	☑
9	Be resistant to manipulation. This includes physical measures such as providing that marks are irremovable and indelible, but also solution design considerations such as non-predictability of unique identifier codes, traceability data reconciliation against other data sources, safeguards against traceability being accessed / used by unauthorised parties; (Article 15, §1)	☑
10	Enable Member States and EU authorities to monitor and survey the market as per respective mandates (general aim of Article 15 and recital 29);	☑
11	As far as possible, used of solution components currently being used in a commercial supply chain environment and avoid unnecessary burden for business and/or authorities (Impact assessment considerations).	☑

Table 32 –Summary assessment of Traceability Option 2 Against Solution Critical Success Factors

8.4 TOBACCO TRACEABILITY: OPTION 3

Option 3 is a blended solution where the EU Commission mandates minimum standards (for interoperability) and each Member States establishes their own solution requirements, and chooses to appoint either the Tobacco Manufacture or a Solution Provider to implement the system (a similar operating model to Excise Movement and Control System (EMCS)).

8.4.1 KEY PRINCIPLES

- Option 3 considers a solution where Member States prescribe the tobacco traceability solution, whether operated by industry or a solution provider independent of industry and that applies to all tobacco manufacturing and tobacco movements and sales within the Member State.
- The EU Commission mandates the minimum data to be recorded, interoperability standards and provides a means for EU agencies and other Member States to access a Member State's tobacco traceability data under controlled circumstances

to support risk management, enforcement and investigation activities within the EU community.

- Each Member State appoints a data management provider as the repository for national tobacco traceability data.
- EU access to data will be limited to providing a mechanism for data queries to operate across Member State data repositories. Detailed data analysis will be based on requests to the Member State for access to relevant data.
- Distribution chain operators (DCOs) operating within a particular Member State record distribution chain events either using their own systems then submit to the Member State repository using prescribed industry data exchange standards, or use a solution offered by either the tobacco industry or independent solution provider, as applicable for that Member State.

Two variations of this third option are considered:

- Option 3a considers the scenario that different Member States may appoint tobacco manufacturers to operate the tobacco traceability solution.

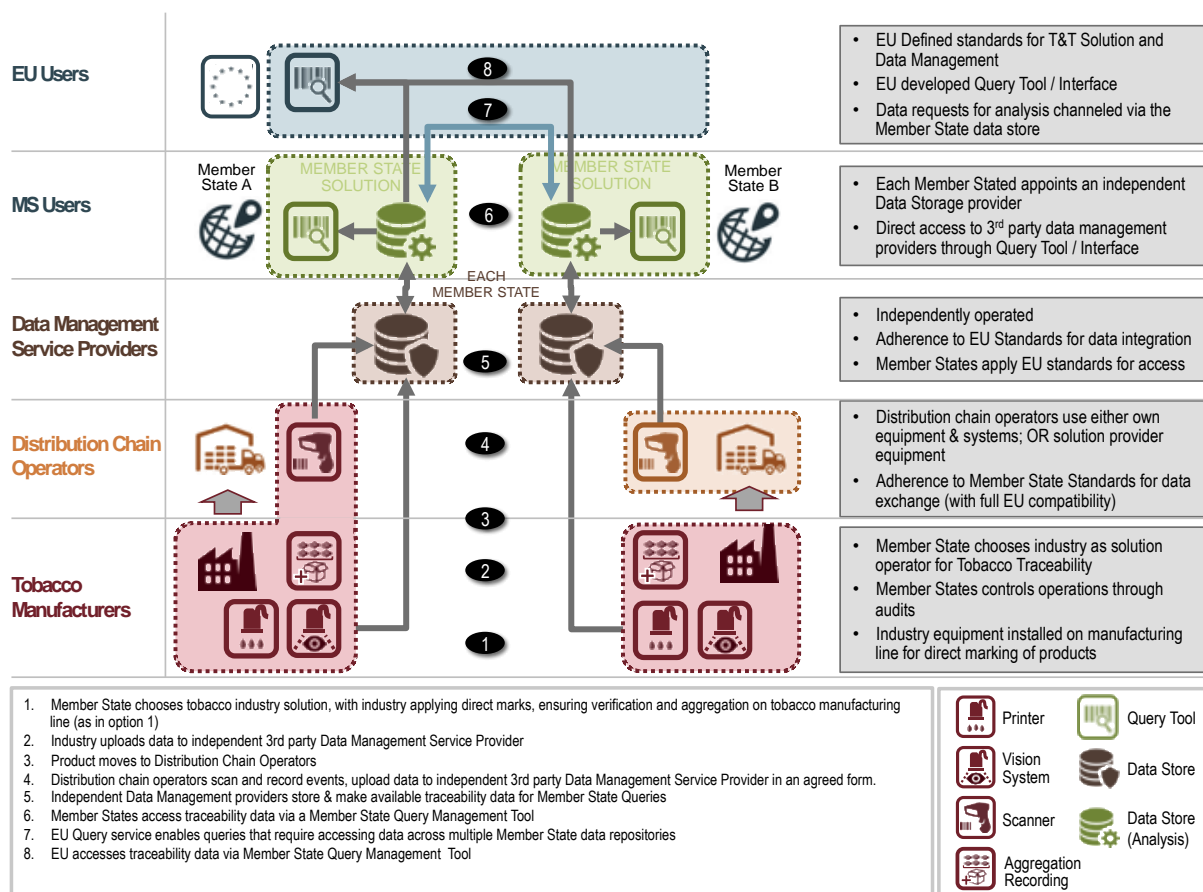


Figure 41 – Overview of Solution Option 3a

- Option 3b considers each Member State appointing their own solution provider (independent of the tobacco industry).

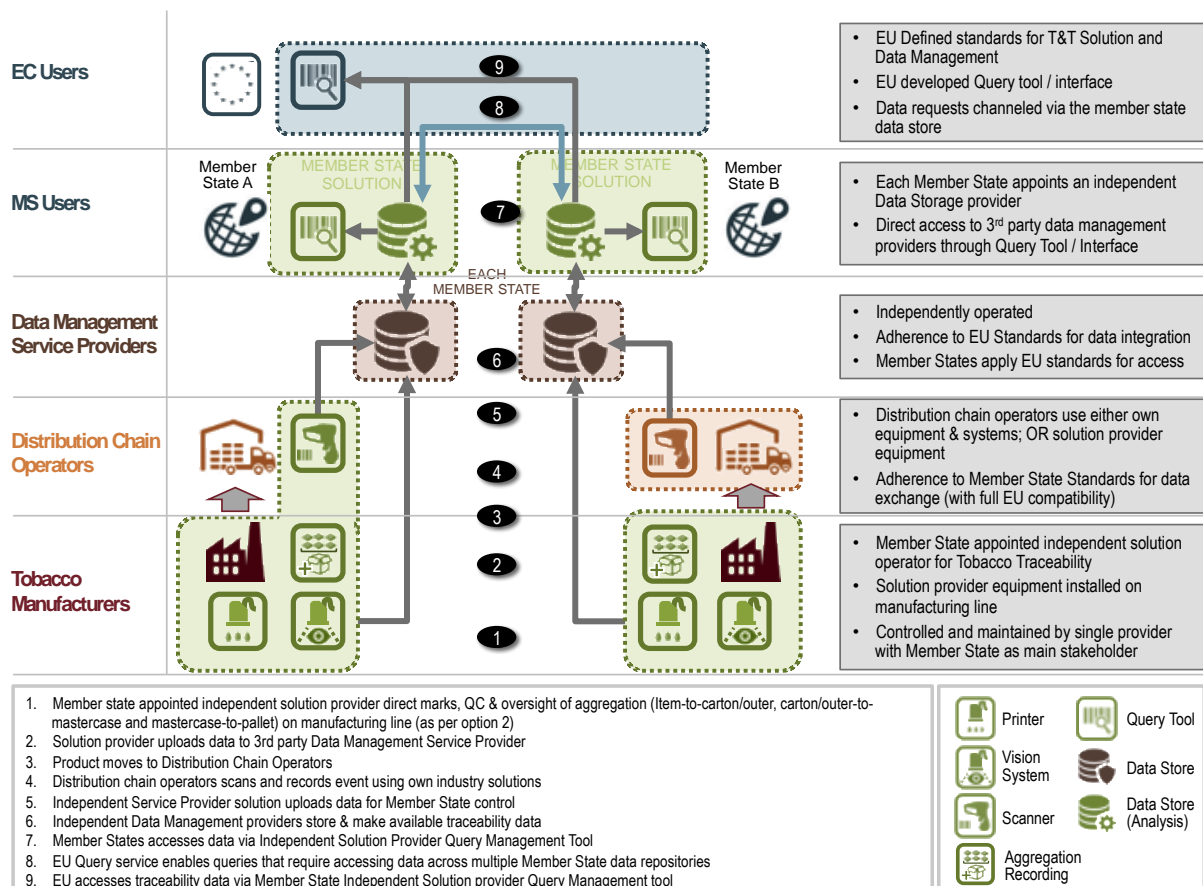


Figure 42 – Overview of Solution Option 3b

8.4.2 OVERVIEW

In the blended solution, Member States assign the verification of production and use of unique identifiers to a party independent of the tobacco manufacturer considering both these as critical and high risk elements of the traceability solution for a tobacco control regime.

The EU dictates what minimum information should appear on tobacco packs, marking symbology for tobacco items and packaging (for interoperability of the traceability solution across Member States). Member States lay down, on the basis of an EU agreed set of technical specifications, the standards for the serialisation of tobacco products at unit level, recording aggregation operations and identifiers of secondary and tertiary packaging and quality control. Depending on Member State preference, the solution can either be operated by the tobacco industry or by a solution provider independent of tobacco manufacturers.

Given this flexibility for Member States to appoint the operator of the solution, it is recommended that this assignment applies to marking of tobacco products manufactured in that Member State only. In other words, a Member State would not require that all tobacco products that retail in its territory be marked by that solution provider, as this would require the solution provider to install their solution on all production lines (even outside the Member State’s territory). Applied to each and every Member States, this could potentially result in production line producing an EU-wide brand needing to be outfitted with 28 different solution provider solutions. The importance for this is discussed further in 8.6.3 below. Further, the EU Commission and Member States would need to agree which solution would be used for tobacco traceability of products imported into the EU.

Direct marking is used as the default method for marking units of tobacco products at the time of manufacture using a quality control mechanism.

Distribution chain operators are required to record logistics event updates and submit these together with associated commercial information as tobacco products move through the distribution chain. This is achieved either by using their own systems that meet required standard and submit this using an EU prescribed form, or by using a separate system provided by the tobacco industry or solution provider, as may be relevant for that Member State.

Oversight by Member States and EU authorities is mixed, potentially provided by tobacco manufacturers in some Member States, and potentially by a solution provider independent of the tobacco manufacturers in others.

Member State enforcement agencies use traceability tools developed by the respective operator to read and decode pack markings and access tobacco tracing information, and a minimum set of traceability data is shared with EU enforcement agencies. Compatibility requirements are specified to allow query tools of one solution to provide queries on tobacco products that may have been commissioned in other Member States operated by a different solution. Government authorities at both the EU Community and Member State level actively use traceability data for monitoring and oversight purposes, with services in place to aggregate data for analysis purposes from each Member States repositories.

8.4.3 IMPLICATIONS

Note: Requirements that are very similar or identical to those identified previously and common across the traceability options have been included in Grey to aid identification of the primary differences.

Stakeholder	Option 3: Solution Requirements
 <p data-bbox="188 1317 387 1373">Tobacco Manufacturers</p>	<p data-bbox="411 1249 635 1283">OPERATIONAL</p> <ul data-bbox="459 1305 1410 1872" style="list-style-type: none"> <li data-bbox="459 1305 1410 1429">▪ Tobacco Manufactures (TMs) are required to maintain and provide the list of brands and products (SKU’s) to the Member States, to then be consolidated by the European Commission and shared with all Member States. <li data-bbox="459 1451 1410 1574">▪ TMs locations will require a unique location identifier requiring each manufacturer to register with an industry association such as GS1 to obtain prefixes and to assign a GS1 GLN and extension component for individual production lines. <li data-bbox="459 1597 1410 1720">▪ TMs must use packaging designs for unit packets of tobacco products that need to be adapted to accommodate an area for application of the unique identifier that meets the manufacturers / solution provider(s) provided specifications. <li data-bbox="459 1742 1410 1832">▪ TMs must use cartons and bundle packaging designs that accommodate the application of a machine-readable and human readable serial code (aligned to aggregation requirements). <li data-bbox="459 1854 1410 1872">▪ TMs will need to make available information required for the

Stakeholder Option 3: Solution Requirements



Tobacco
Manufacturers
- continued

generation of the unique identifier containing data elements required in Article 15 §3¹⁰³. The envisioned operational impact will further require either:

- Solution Provider / Manufacturers solution to provide a terminal / user interface for manufacturers operators to setup and capture information as part of shift setup (e.g. Intended market of retail sale); or
 - Provide an interface for manufacturers to provide messages from their production systems to receive the required information electronically for the coding operations.
 - Scanning of the retail barcode (EAN / GTIN) on the tobacco product unit as where part of an automated solution operated by the solution provider(s) to reference required master data to determine the product description and intended market of retail sale.
 - Some potential issues with information available and feasible for encoding as part of the unique identifier are discussed further in section 8.6.2 below.
- TMs must modify dispatch operations to require the unique serial numbers of the shipping items (at highest aggregation level) be recorded when shipments are staged and /or loaded, with the same operational requirements identified as identified for Option 1.
 - An order number would need to be linked to the unique identifier of the pallet, master cases or cartons being prepared for shipping be linked to the specific order number.
 - TMs will need to have on record the unique references numbers that identify customers and their storage facilities to which goods may be shipped (potentially using global supply chain standards such as GS1 GLN)
 - **Note:** These dispatch operations would already be performed to some degree by those manufacturers with agreements with the EU, requiring the tracking of tobacco shipments to the 1st customer, whether currently at pallet or master case level. This operational impact would now be standard across all tobacco manufacturers).
 - TMs are required to have exception processes in place, to record damaged or unsellable goods (various stages of aggregation).
 - As with Option 1, TMs will require business processes to support the submission of commercial event data (invoice and payment records) to the data management providers.

In Member States where the TMs are appointed to operate the tobacco traceability solution:

¹⁰³ See footnote 37 on page 48 above.

Stakeholder Option 3: Solution Requirements



Tobacco
Manufacturers
- continued

- As in Option 1, TMs themselves will be responsible for sourcing and implementing equipment on each production line for coding (serialisation), aggregation, data collection and submission, and operating automated quality controls, business process quality controls and associated rejection and exceptions management processes.
- TMs will be responsible for maintenance and upkeep of tobacco traceability related equipment (whether self or agreements with OEMs) and required operation consumables.

In cases where the Member State appoints a solution provider (option 3b):

- TMs will need to accommodate within reason, representatives of the solution provider(s) being allowed access to production areas for the purposes of operation, maintenance and support of the tobacco traceability solution components.
- TMs may be requested to make available a space that can be secured and locked, suitable for the installation of server and communication equipment operated by the solution provider(s), as well as network connectivity from the allocated server room to the production lines.
- TMs responsible for operation and maintenance of network connectivity at each production site, for use by the solution provider(s) systems.
- TMs advise solution provider(s) of maintenance schedules (to optimise tobacco traceability solution maintenance times and minimise impact on manufacturers).
- TMs must have exception processes in place, with the Solution Provider(s) providing a system / mechanism for manufacturers to record damaged or unsellable goods (various stages of aggregation).
- TMs outside of the EU manufacturing for the EU market will need to implement a solution operated by an EU and Member State agreed operators and conform with required tobacco product item marking, aggregation recording and traceability information event submission.
 - This may require a mechanism for the EU commission to review of the tobacco traceability solutions that may be implemented in other non-EU countries, and the degree to which this meet the requirements for products placed onto the EU internal market;
 - **Note:** Countries outside the EU that intend to export tobacco products to the EU will have to comply with EU legislation. It is recognised that beyond this scope, EU traceability requirements cannot be imposed on manufacturers of tobacco product in countries outside the EU that do not intend to import to the EU. In the case these products are brought illegally onto the EU internal market, there remains the need for internationally agreed standards as a traceability minimum, by preference

Stakeholder Option 3: Solution Requirements

Tobacco
Manufacturers
- continued

agreed under the FCTC protocol.



- This may require the solution provider(s) to install and maintain the required equipment in these locations.
- Requires a method to assign these costs to / between tobacco manufacturers and to ensure off-shore production is of significant quantities to justify this capital costs.
- As with Option 1, it is anticipated that marking of products on arrival in the EU territory would in most cases not be feasible.



TECHNICAL

- TMs extensions to financial accounting systems will be required to export commercial transaction information including invoice, order number, and payment records:
 - In the case of 3a, this will require a mechanism for the TM's system to submit this data as part of the tobacco traceability data.
 - In the case of 3b, the solution provider(s) application will use this information to link the unique identifiers of the pallets, mastercases and/or cartons during the order dispatch process.
 - It is anticipated that the extent of commercial data to be exported may have significant implications; these are discussed further in 8.6.9 below.

Where the TMs operate the solution (3a), as outlined in Option 1 above:

- As Option 3 considers an environment where different manufacturers and Member States potentially use different solutions, it is proposed that the EU consider allocating a unique prefix solution provider, with the requirement that this be prepended to the generated unique identifier.
- Data is transmitted to the Member State data management providers in agreed form (e.g. GS1 EPCIS standard with agreed extensions to accommodate TPD Article 15 data elements).
- Implement quality measure controls in terms of readability of the machine readable codes on tobacco items and packaging (compliance with the specification for the agreed symbology, as well as relevant quality measure standards, such as ISO/IEC15415:2011 - Automatic identification and data capture techniques -- Bar code symbol print quality test specification 2D symbols, similar AIM DPM [used for data matrices] or equivalent)
- TMs install and operate required equipment for marking of tobacco items with the unique identifier (recommended both a machine readable and human readable), the quality control system and aggregation recording equipment (pack through to pallet).
- To ensure integrity of aggregation events, aggregation stations for pack-to-carton and carton-to-master case should include physical and logic safeguards such as shields, covers, doors

Stakeholder	Option 3: Solution Requirements
 <p data-bbox="188 356 384 450">Tobacco Manufacturers - continued</p>	<p data-bbox="507 280 1394 409">(including cabinet open / close sensors) to prevent potential interference or tampering (intentional or unintentional) that may affect the certainty of recording the correct “child” items with the associated “parent” container.</p> <p data-bbox="411 427 1114 461">Where a solution provider has been appointed (3b):</p> <ul data-bbox="459 479 1406 651" style="list-style-type: none"> <li data-bbox="459 479 1406 577">▪ Depending on solution implementation method, system interface to advise solution provider system of scheduled production information (e.g. intended market, product type). <li data-bbox="459 589 1406 651">▪ Site network connectivity and power supply to support solution provider(s) on-site equipment) <p data-bbox="411 730 1278 792">POTENTIAL LEGISLATIVE CONSIDERATIONS FOR EU AND MEMBER STATES IN RELATION TO MANUFACTURERS</p> <ul data-bbox="459 815 1374 1178" style="list-style-type: none"> <li data-bbox="459 815 1374 878">▪ Legal basis required for fitment of tobacco traceability components on manufacturers production lines. <li data-bbox="459 891 1374 954">▪ Requirements to keep and record tobacco production, sale and movement data (for supporting verification and audit purposes) <li data-bbox="459 967 1374 1066">▪ Policy in place for Member State / EU agency sign-off of manufacturers implementation (operational readiness assessment) <li data-bbox="459 1079 1374 1178">▪ Consideration of remedial measures, penalties, sanctions or potential legislative actions against manufacturers by EU and Member State authorities where non-compliance is identified.
 <p data-bbox="188 1348 384 1411">SME Manufacturers</p>	<p data-bbox="459 1272 1358 1370">In addition to the requirements identified above, the following are special considerations for Small and Medium Enterprise manufacturers (SMEs) that may have low levels of automation:</p> <ul data-bbox="459 1388 1401 2011" style="list-style-type: none"> <li data-bbox="459 1388 1401 1487">▪ As in Option 1 above, for low volume producers and some other tobacco products not suitable for direct marking, a solution using labels may be used. <li data-bbox="459 1498 1401 1899">▪ Low levels of systemisation and / or use of consumer invoicing and accounting software with little opportunity for extension and customisation may necessitate the use of a stand-alone system. In option 3a there may be an opportunity for the development of a common SME tobacco manufacturers option, as an alternative for SME’s to develop own bespoke solutions if this is not the case. For option 3b, the solution provider may a stand-alone system to SME’s for the capture of information required for tobacco traceability purposes. <ul data-bbox="555 1800 1369 1899" style="list-style-type: none"> <li data-bbox="555 1800 1369 1899">○ As with Option 1, duplicate capturing activities will have an operational impact of additional time required for the capture of information into the traceability system <li data-bbox="459 1910 1401 2011">▪ As in Option 1 and 2 above, SMEs may need to procure (Option 3a) or be provided (Option 3b) handheld devices capable of reading the machine-readable unique identifier on unit packets of

Stakeholder	Option 3: Solution Requirements
 <p>SME Manufacturers - continued</p>	<p>tobacco, and to support manual aggregation processes, where a further operational impact is envisaged in the additional time required to scan each item during packing operations.</p>
 <p>Solution Provider (Where appointed by Member States)</p>	<p>OPERATIONAL</p> <ul style="list-style-type: none"> ▪ As in Option 2, where Member States appoint a Solution Provider (SP), this entity will be responsible for sourcing and implementing equipment on each production line for coding (serialisation), aggregation, data collection and submission, and operating automated quality controls, business process quality controls and associated rejection and exception management processes. ▪ The SP will be responsible for maintenance and upkeep of their tobacco traceability related equipment and required operation consumables. ▪ As in Option Two, the SP will be required to provide support to tobacco manufacturers and distribution chain operators ▪ The SP solution should monitor and report on the tobacco items where the unique identifier is absent or unreadable and indicate if required EU prescribed service levels are achieved. ▪ As in Option 2, an EU and Member State policy should take into consideration the possibility that a manufacture may be able to utilize their existing traceability solution equipment if it meets all requirements. ▪ To minimise impact on manufacturers, mechanism should be in place for SPs to monitor all operating sites to ensure tobacco traceability equipment is operating within acceptable parameters, action operational alerts, schedule required and preventative maintenance. ▪ SPs must provide support to EU and Member State authorities. <ul style="list-style-type: none"> ○ Provide query management tool and interface for authorised parties to access tobacco traceability data. ○ Assist with information requirements for audit, inspection and enforcement activities. <p>TECHNICAL</p> <ul style="list-style-type: none"> ▪ SPs implement required serialisation components that meet EU Standards for unique identifier composition. <ul style="list-style-type: none"> ○ As identified above, to accommodate the different potential Member States solution in operation, it is proposed that the EU consider allocating a unique prefix to




Stakeholder Option 3: Solution Requirements


Solution
Provider
- continued

each solution provider, with the requirement that this be prepended to the generated unique identifier¹⁰⁴.

- Downstream there will be a requirement for interoperability in any mobile apps or query management tools.
- SPs must meet EU prescribed requirements for interoperability:
 - Recognised industry standards for the machine-readable symbology / data carrier used for the unique identifier on tobacco items and serial identifiers on packaging (cartons, mastercases and pallets). Standards agreed for EU to allow reading and decoding by downstream economic operators and EU and Member State authorities.
 - Data transmission to data management providers is in agreed form (e.g. GS1 EPCIS standard with agreed extensions to accommodate TPD Article 15 data elements).
- As in Option 2, it is recommended that:
 - The SPs are required to implement quality measure controls.
 - SPs ensure that all solution components and cabinets installed at manufacturers' and distributors be protected against access by unauthorised parties.
 - SPs provide alternative solution for application of the unique identifier where direct marking may not be suitable, including small / low volume producers and / or producers of other tobacco products.
 - SPs provide handheld scanners / reading devices for small manufacturers and distribution chain operators to meet tobacco traceability requirements
 - SPs install and operate required equipment for marking of tobacco items with the unique identifier (recommended both a machine readable and human readable), the quality control system, aggregation recording equipment (pack through to pallet), as well as necessary servers at manufacturing sites.
 - SPs develop and maintain a tobacco traceability query application that may be operated by EU and Member State authorities to support query, inspection and audit functions.
 - SPs provide a system interface for EU and Member State authorities to access traceability data for analysis, as well as business intelligence and reporting tools to provide oversight of the tobacco manufacture and distribution chain.

¹⁰⁴ For further consideration of ensuring identifies for items are unique see ISO 15459 (1-8) -- Information technology — Unique identifiers

Stakeholder	Option 3: Solution Requirements
 <p>Solution Provider - continued</p>	<ul style="list-style-type: none"> ○ SPs meet information and record keeping requirements to support normal state supervision controls. ▪ SPs adhere to strict confidentiality requirements to protect information on tobacco manufacturer's production, production capacity (planned or actual) with parties other than authorised EU and Member State authorities. <p>POTENTIAL LEGISLATIVE CONSIDERATIONS FOR EU AND MEMBER STATES IN RELATION TO SOLUTION PROVIDER(S)</p> <ul style="list-style-type: none"> ▪ SPs adhere to information and record keeping requirements: <ul style="list-style-type: none"> ○ Records on system operation including items marked, quality of markings, aggregation events and received associated commercial information (e.g. orders, invoices and purchase records) ○ Provide regular information verification activities (including reconciliations) to ensure the tobacco traceability solution is operating correctly. ▪ Where applicable, standard service provider contract management considerations related to the solution provider(s)
 <p>Distribution Chain Operators</p>	<ul style="list-style-type: none"> ▪ In this Option, Distribution Chain Operators (DCOs) will have the same operational, technical and legal implications and requirements as envisaged in Options 1 and Option 2 apply, with the primary distinction being the party that provides support and the solution for use by small / non-automated distributors. ▪ Further, to accommodate the number of different data management providers (as considered under option 1, 3 and 4), DCOs will be required to use a discovery service, which will apply the predefined business logic to route submitted distribution chain events to the relevant Member State repository.
 <p>Data Management Provider(s)</p>	<p>OPERATIONAL</p> <ul style="list-style-type: none"> ▪ Data Management Providers (DMPs) will provide a data hosting service in the Union in line with contracts concluded with the respective Member State. ▪ As in Option 1 and 2, the DMP will be required to: <ul style="list-style-type: none"> ○ Administer user rights and security access. ○ Provide a pilot / test environment for use by solution provider(s) and distribution chain operators to test system changes and enhancements. ○ Maintain audit logs that record access and activity related to all accounts ▪ DMP provides access to external auditors as necessary for their purpose to monitor activities related to the DMPs.

Stakeholder Option 3: Solution Requirements

Data
Management
Provider(s)
- continued

TECHNICAL

- DMPs must adhere to requirement for an EU-wide standard that enables the correct repository to be identified in order to determine the correct destination for a traceability event message. Further, for multiple DMPs it is recommended that a discovery service be implemented to route traceability events and queries to the appropriate event repository.
- As in Option 1, DMPs will need to:
 - Implement support for industry standards for information exchange, such as EPCIS for traceability events, and EDI formats for receiving of commercial documents (invoice, order and payment records).
 - Implement a robust security model governing which parties may update records, specifically with restrictions to prevent amendments and changes to existing records by tobacco manufacturers and distribution chain operators.
 - Provide an interface for authorised EU and Member State authorities to export tobacco traceability events to another repository for analysis.
 - Implement secure data transmission and encryption techniques to be used for all received and transmitted data.

POTENTIAL LEGISLATIVE CONSIDERATIONS FOR EU AND MEMBER STATES IN RELATION TO DATA MANAGEMENT PROVIDERS

- DMPs must adhere to data storage confidentiality requirements for each Member State, duration of storage, tiered storage, access control, back-ups, business continuity and disaster recovery.
- DMPs agreements should include SLAs specifying availability and performance requirements.
- Standard service provider contract management considerations related to the data management provider(s)



Member State
Authorities

OPERATIONAL

- For option 3b, Member State Authorities (MSs) are responsible for appointing operator of tobacco traceability solution at point of tobacco manufacture:
 - Operation of bid and selection processes.
 - Develop a review period and framework for conducting a basic audit of solution provider(s) activities:
 - Performance against Service Level Agreements (SLA) and Key Performance Indicator (KPI) monitoring.
 - Audit of tobacco traceability information (sampling

Stakeholder Option 3: Solution Requirements


Member State
Authorities
- continued

of items to validate recorded information) to validate integrity of solution.

- MSs are responsible for identifying a data management provider to provide a repository for tobacco traceability events relevant to the Member State.
 - Operation of bid and selection process.
 - Contract management of service provider for suggested considerations, see section 10 below.
- MSs are given access to tobacco traceability data to support authorities' monitoring, reporting, surveillance and enforcement activities.
- MSs conduct regular market surveillance campaigns to verify compliance of EU manufactured products and assess levels of illicit items on the internal market.
- Particularly in the case of option 3a, its MS may need to facilitate joint Government and Industry working group to support and maintain specifications and standards. A critical function of the group during solution development implementation and post implementation is to provide a platform for tobacco manufacturers and distribution chain operators to resolve identified issues and track implementation progress.
- MSs operate a solution for query and analysis of tobacco traceability data. Development of solution either by Member State, tobacco manufacturer (Option 3a) or solution provider (Option 3b).
 - Access to tobacco traceability data is used to support Member State authorities' monitoring, reporting, surveillance and enforcement activities.
- MSs party to the WHO FCTC Protocol may wish to utilise access to tobacco traceability data for the purposes of responding to enquiries received through the global information-sharing focal point.
- Where the manufacturing industry is appointed to operate the traceability solution, extension of MSs supervision controls as recommended in Option 1 apply, with the associated operational impact.
- Stakeholder education and consumer-awareness campaign activities related to introduction of tobacco traceability solution (and logically these activities may be combined with activities to promote consumer education of security feature).

TECHNICAL

- MSs able to access tobacco traceability data through either:
 - Query Tool developed by Member State, or by tobacco manufacturers (Option 3a) or solution Provider (Option 3b); or
 - A technical interface provided by the data management provider for exporting tobacco traceability data to a

Stakeholder Option 3: Solution Requirements


Member State
Authorities
- continued

Member State authority operated repository.

- In the case of a solution provider(s): Business intelligence and reporting tool provided by the provider(s) to ensure oversight of the tobacco distribution chain (at Member State level), including alerts and reports to support / aid Member State authorities current state supervision controls.
- In the case of appointing the tobacco industry, it is recommended MSs are responsible for creating their own tobacco distribution chain monitoring applications to use traceability data accessible from the 3rd party data management provider).
 - **Note:** To ensure market surveillance, investigation and enforcement activities remain effective, traceability data requests should remain confidential to trusted parties only, and all tobacco traceability data requests, decryption and analysis should be processed independently of any tobacco manufacturing or distribution economic operator's systems.

POTENTIAL LEGISLATIVE IMPLICATIONS

- MSs are provided authority and a legal basis to access tobacco manufacturer and distribution chain operator compliance. Will require legal basis to access premises, areas of tobacco production, storage facilities, information and request additional supporting documentation where required. This will be required for inspection of tobacco products under suspension of, or post-payment of any relevant duties and taxes.
- For option 3b, legislation to prohibit tampering, adjustment and movement of Solution Provider's equipment without prior notification and approval.
- MSs are provided authority and legal basis to access distribution chain facilities for the purposes of assessing the compliance of these economic operators with tobacco traceability obligations.
- MSs consider legal basis and sanctions to enforce technical standards for unique identifier composition, pack / item marking, secondary unit marking (e.g. carton), mastercase marking and pallet marking, together with aggregation events.
- MSs consider legislation to enable submitted tobacco traceability data to be used by other EU agencies, national agencies / departments where a benefit of national interest can be demonstrated.



EU Authorities

OPERATIONAL

- EU Authorities (EU) has access to tobacco traceability data to support current EU authorities' monitoring, reporting, surveillance and enforcement activities (using either MS provided systems where access is granted, or by means of a EU query management tool developed and overseen by the EU Commission, and/or by

Stakeholder Option 3: Solution Requirements

EU Authorities
- continued

means of an interface provided to export traceability data).



- EU conducts review of suitability of proposed data management providers for approval to operate a data storage repository for all relevant tobacco traceability data at Member State level.
- EU supports and maintains interoperability standards of tobacco traceability solutions implemented in Member States
- EU reviews and approves the external auditors responsible for monitoring activities of the data management provider.

TECHNICAL

- As in Option 1 and 2, the EU prescribes minimum standards for interoperability in serialisation and data aggregation and standards for interoperability of data exchange: Form by which tobacco traceability data is submitted by the solution provider(s) and/or tobacco manufacturers to the data management providers:
- The EU is responsible for operating a data exchange layer for routing tracing queries that may span between two or multiple Member State repositories. This would also need to also ensure that authentication requests are authorized or allowed, that communication is authorized or allowed, and that the query is routed to the appropriate repository, considering query processing rules under ISO16678:2014(E), Guidelines for interoperable object identification and related authentication systems to deter counterfeiting and illicit trade.
- Similar to the Member State authorities, EU will be able to access tobacco traceability data through either a Query Tool operational in each Member State (either developed and overseen by the Member State [Option 3a], or provided by the Solution Provider appointed in that Member State [Option 3b], as well as a technical interface for exporting tobacco traceability data to an EU authority operated data repository.
- If required, the EU Authorities may designate a provider of additional applications to use traceability data accessible from the 3rd party data management provider.

POTENTIAL LEGISLATIVE IMPLICATIONS

- EU considers legal basis and sanctions to enforce technical standards for unique identifier composition, pack / item marking, secondary unit marking (e.g. carton), mastercase marking and pallet marking, together with aggregation events.
- Legal base for EU Authorities to access to tobacco traceability data to support relevant authorities to perform assigned monitoring, reporting, surveillance and enforcement responsibilities.
- EU considers legislation to enable submitted tobacco traceability data to be used by other national agencies / departments where a benefit of national interest can be demonstrated.
- EU creates legal basis for solution provider(s) to request access

Stakeholder	Option 3: Solution Requirements
 EU Authorities - continued	to manufacturer's premises, install and maintain equipment on production lines and be provided access to power and network connectivity (Option 3b)
 Consumers	It is not expected that there are any material implications resulting from Option 3a or 3b that will impact consumers.

8.4.4 KEY CONSIDERATIONS

An analysis, including a security audit of existing solution provider applications (code generator, line software, ERP systems etc.) for the creation and recording of serialised marks was not in scope for this feasibility study. While general mechanisms should be implemented to ensure the correct operation of the traceability solution, the scope for a largely automated control may include the reconciliation of summary traceability data recorded by the independent solution provider against the declarations for excise tax purposes made by the tobacco manufacturers. Further, reconciliation with an additional data source may include the volumes of security feature elements used, and where in operation in a member state, the volumes of tax stamps used.

8.4.5 CONSIDERATIONS IN THE CONTEXT OF THE WHO FCTC PROTOCOL

For considerations and recommendations related to Option 3a, please see section 8.2.5 above. It is anticipated that Option 3b could be implemented in a manner compatible with the Protocol.

8.4.6 KEY ADVANTAGES AND DISADVANTAGES

Advantages	Disadvantages
<ul style="list-style-type: none"> ▪ High levels of autonomy and choice for Member States. ▪ Increased competition and market opportunity as solution scale required at Member States increases opportunity for medium solution providers to participate. ▪ Limited dependency allows individual Member States to implement national solutions as and when ready. ▪ Member States have flexibility in level of independence and level of control to impose on Manufacturers. 	<ul style="list-style-type: none"> ▪ Potential fragmentation of solution providers and data management providers reduces economies of scale benefit and increases costs. ▪ Solution has very high dependence on interoperability amongst numerous providers and data integration across multiple sources. ▪ Risk of incompatibility and data integration issues during initial implementation. ▪ Integration of Member State level solutions required to provide EU-level oversight and tools for EU Agencies. ▪ Potential system performance disadvantages when conducting tracing queries that span multiple Member State repositories. ▪ Member States importing tobacco products dependent on readiness of producing Member States. ▪ For 3a: Risk is that the system might not provide reliable guarantees for independent control and management of the codes at pack level. ▪ For 3a: It remains an open question whether the actual shared industry software components are free from vulnerabilities and functions that may compromise its integrity.

8.4.7 COMPATIBILITY WITH SOLUTION CRITICAL SUCCESS FACTORS

A summary review of traceability option 1 against the critical success factors identified as part of the problem statement is presented below.

1	Ensure each pack is marked with a unique identifier (Article 15, §1);	☑
2	Provide an accurate mechanism for recording the movement (tracking) of tobacco products through the point of manufacture to the last economic operator before retail (Article 15, §5);	☑
3	Support the concept of aggregation (Article 15, §5);	☑

4	Store data independently (not by the tobacco industry) (Article 15, §8 and recital 31);	Option 3a	<input checked="" type="checkbox"/>
		Option 3b	<input checked="" type="checkbox"/>
5	Ensure that the systems used for the unique identifier and the related functions are fully compatible with each other across the European Union (Article 15, §11b);		<input checked="" type="checkbox"/>
6	Protect confidentiality and safeguard that decoding and full access to the data storage facilities limited to authorised authorities and only exceptionally in duly justified cases to tobacco industry under restrictive conditions (article 15, §8);		<input checked="" type="checkbox"/>
7	As far as possible, be compatible with current tobacco production, packaging and the trade environment to minimise the impact on tobacco production taking into consideration production speeds, equipment, etc. (internal market proportionality obligations)		<input checked="" type="checkbox"/>
8	Uphold respect for data protection as specified in the EU legal framework (Directive 95/46/EC) (Article 15, §10);		<input checked="" type="checkbox"/>
9	Be resistant to manipulation. This includes physical measures such as providing that marks are irremovable and indelible, but also solution design considerations such as non-predictability of unique identifier codes, traceability data reconciliation against other data sources, safeguards against traceability being accessed / used by unauthorised parties; (Article 15, §1)	Option 3a	<input checked="" type="checkbox"/>
		Option 3b	<input checked="" type="checkbox"/>
10	Enable Member States and EU authorities to monitor and survey the market as per respective mandates (general aim of Article 15 and recital 29);		<input checked="" type="checkbox"/>
11	As far as possible, use solution components currently being used in a commercial supply chain environment and avoid unnecessary burden for business and/or authorities (Impact assessment considerations).		<input checked="" type="checkbox"/>

Table 33 –Summary assessment of Traceability Option 3 Against Solution Critical Success Factors

Critical success factors 4 and 10 both received amber markings, showing that they could be compatible but with some open issues requiring consideration for option 3a. Please see the discussion on these items in section 8.2.7 above.

8.5 TOBACCO TRACEABILITY: OPTION 4

A solution that combines the traceability solution with security features by adding a unique identifier to the security feature.

8.5.1 KEY PRINCIPLES

- Synergies between the traceability solution and security feature can be realised. Further synergies and cost savings for those Member States that have Tax Stamps / Fiscal markings that will fulfil the requirements of the security feature in TPD Article 16, and therefore will enable these to be used for this purpose.
- A tobacco control traceability solution which requires that some critical elements be controlled by the Member States, whilst less critical functions can be delegated to an independent provider OR other players:
 - Member States retain key responsibilities considered critical for a tobacco control regime and establish solution components and standards for

recording the unique identifier of the secure label applied during manufacture. This equipment is installed in manufacturing premises but operated and serviced by a provider independent of the tobacco industry. A data exchange mechanism is specified for manufacturers to provide additional data at time of manufacture (e.g. intended shipment route).

- o Solution components that are considered lower risk such as recording distribution chain events from manufacture to last point prior to retail are operated by industry and data is submitted to the independent Data Management Provider using prescribed industry data exchange standards.
- EU Commission dictates the minimum data to be recorded and provides a means for EU agencies and other Member States to access this data under controlled circumstances to support risk management, enforcement and investigation activities within the EU community.
- An independent Data Management Provider(s) appointed by the Commission and/or each Member State stores traceability data (recorded at the time of manufacture or import, and received from the distribution chain operators).

EU operates a query messaging service for the routing of tracing queries that span multiple Member State data repositories.

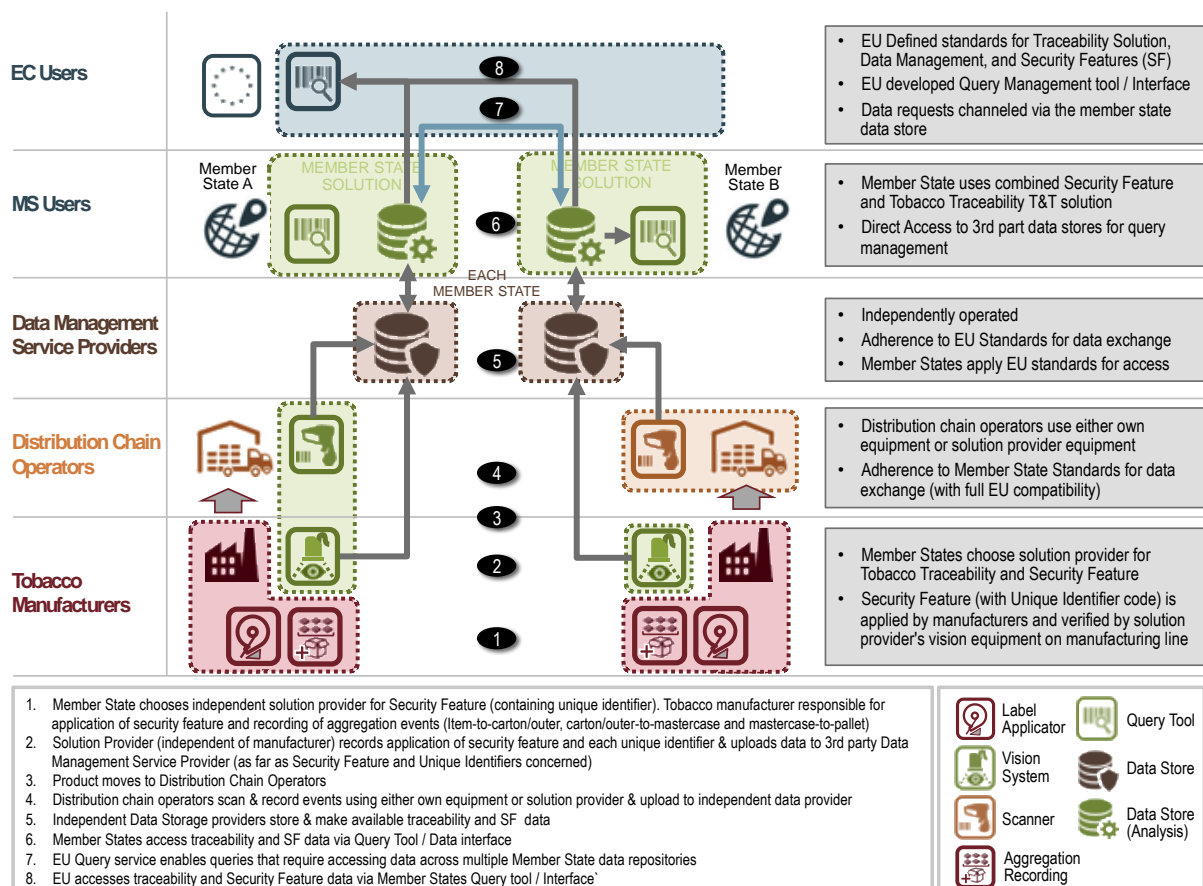


Figure 43 – Solution Option 4

8.5.2 OVERVIEW

In Option 4, Member States establish a control of the unique identifiers used at the time of tobacco product manufacture, a key risk for a tobacco control regime. The EU

prescribes the security feature and the minimum information that should appear on tobacco packs, as well as markings for cartons / bundles, mastercases and pallets for interoperation of the traceability solution across Member States. Member States may prescribe additional requirements for serialisation (applied to the security feature) tobacco pack marking, carton marking and quality control. The vision system, or other validation system, on the production line ensures the security feature has been applied, records the unique identifier, additional data elements (such as production line and time of manufacture) and stores this information. A solution provider independent of the tobacco manufacturers operates this vision system, or other validation system.

The method for marking of secondary and tertiary packaging is operated by the tobacco manufacturer, together with the aggregation recording mechanisms. The traceability data related to the produces is therefore created and managed by the independent provider, whilst the data related to aggregation of the products into packaging for shipment is recorded by the tobacco manufacturers, with an opportunity for integrity of the solution to be verified by reconciling the two.

Distribution chain operators use industry chosen technologies and systems to record logistic event updates as tobacco products move through the distribution chain, and this data is provided to the independent operator using open industry standards (prescribed by the Member States).

Oversight by Member States and EU authorities is enabled by independent control of traceability data generated at the time of manufacture, and through logistic events recorded from distribution chain operators. Member State enforcement agencies use traceability tools developed by the independent solution provider to read and decode pack markings, and access tobacco tracing information, and a minimum set of traceability data is shared with EU enforcement agencies. Government authorities at both the EU Community and Member State levels actively use all traceability data for monitoring and control purposes.

RATIONALE

Option 4 addresses two main pressure points that may restrict the available technologies that can be applied and may adversely affect solution costs:

- The amount of additional data included within the physical mark on tobacco packs and the ability to apply this mark reliably without adversely impacting high production line speeds; and
- Treating the traceability solution components independently of the security feature impedes potential synergies such as cost savings from reducing hardware and software to be installed on every tobacco production lines (for code generation and printing / marking variable data onto every unit of tobacco product).

Further, the majority of EU tobacco products today are already subject to the requirement of a tobacco tax stamp / fiscal marking. These marks already incorporate numerous security features to reduce the risk of counterfeiting these marks. Article 16 of the TPD provides an option for Member States to integrate the requirement for the security feature with these where suitable. Given the considerations above, the fourth option provides a synergy option that leverages the same label applicators and related systems and infrastructure already being used for fiscal marking, with the addition of a camera vision system, or other validation system, to also fulfil requirements for the traceability solution.

This option **does not** require those Member States that do not have tax stamps today to implement these. The security Feature, which contains the unique identifier, would still need to be applied in these markets, and would still serve the combined purposes of authentication and tobacco traceability.

This option would require the fiscal marking (label, banderol or tax stamp) to be enhanced to include a secure serialised number, making each label uniquely identifiable. This option is also depending to a certain degree on what solution for the security features will ultimately be chosen. The coding and serialisation for the traceability solution takes place at the time the security feature is produced.

At the time of tobacco manufacture, the secure label / stamp would be applied using similar application process as used for tax stamps today. However, in option 4 a camera vision system, or other validation system, is installed on the production line and would perform a dual function. In addition to a quality control function to verify that the security feature has been correctly applied, the camera would also record/capture the unique identifier of each label. It would be able to record the time, manufacturing facility, production line (based on which facility and production line the camera was installed), as well as the product brand and stock keeping unit (obtained by reading the Global Trade Item Number [GTIN] of the tobacco product), thereby creating a complete electronic record of the data elements required at the time of manufacture in terms of Article 15 § 2 of the TPD.

This proposed solution architecture does constrain the information that can be encoded offline as part of the unique identifier code itself (to that which would be known at the time of secure label production, and might include items such as the manufacturer, product type, intended country of sale), however the additional data (such as production date and time) can be recorded and systematically linked to the unique identifier on the label / stamp at the time of manufacture¹⁰⁵.

It is anticipated that this option offers a reduced capital investment requirement by Manufacturers to equip tobacco-manufacturing lines, whilst offering greater flexibility in available technologies and number of solution providers that can offer different components of the traceability solution and the security feature.

Equipment required for separate Traceability and Security Feature	Equipment required for combined Security Feature and Traceability
<p>Traceability:</p> <ol style="list-style-type: none"> 1. Serialisation hardware and software (generate unique identifiers on the production line at the time of manufacture) 2. Network interface between serialisation module and manufacturers system (e.g. capture intended market) 3. High speed printing equipment 4. Vision system, or other validation system, for printing quality control <p>Security Feature</p> <ol style="list-style-type: none"> 5. High speed label applicator 6. Vision system, or other validation system, for application quality control 	<p>Traceability and Security Feature</p> <ol style="list-style-type: none"> 1. High speed label applicator 2. Vision system, or other validation system, for quality control and recording of manufacture traceability data (product SKU, time, place, line) 3. Data interface / capture (e.g. intended market)

Table 34 - Potential Equipment Savings at Each Manufacturing Site

¹⁰⁵ See footnote 37 on page 48 above.

Note: Option 4 considers that generation of the unique identifier and its production would occur during the production of the security feature element. The same considerations in terms of non-proprietary standards for code generation, data carrier and traceability data exchange would apply, as per traceability options one, two and three.

Therefore, as a practical example for the purposes of illustration, consider a scenario where a Member State elects to combine the requirement for the security feature with its tax stamp that fulfil the required technical standards and functions required by the TPD.

- The security feature/ tax stamp may therefore be produced by the Member States choice of security printer or national printing authority, combining the required overt, covert and forensic security elements.
- Traceability option 4 considers the security feature also as the carrier of the unique identifier for traceability purposes. Therefore, the security printer, national printing authority or another party may then be responsible for printing the unique identifier (variable data) onto each security feature using the same technical standards in terms of method for code generation, how a machine readable code is represented (such as ECC data matrix or ISS dot code), and how the event data is recorded and submitted (therefore taking into consideration the same technical standards in options 1 through 3).
- The combined security feature with unique identifier would then be provided to the tobacco manufacturers for application to the tobacco products during the manufacturing / finishing processes.

8.5.3 IMPLICATIONS

Note: Requirements that are very similar or identical to those identified previously and common across the traceability options have been included in Grey to aid identification of the primary differences.

Stakeholder	Option 4: Solution Requirements
 <p>Tobacco Manufacturers</p>	<p>OPERATIONAL</p> <p>Similar to Option 3, the following requirements will apply to manufacturers:</p> <ul style="list-style-type: none"> ▪ Tobacco Manufactures (TMs) are required to provide and maintain the list of brands and products (SKU's) to the Member States, and consolidated by the European Commission to be shared with all Member States; ▪ TMs location will require a unique location identifier requiring each manufacturer to register with an industry association such as GS1 to obtain prefixes and to assign a GS1 GLN and extension component for individual production lines. ▪ TMs cartons and bundle packaging designs are required to accommodate the application of a machine-readable and human readable serial code (aligned to aggregation requirements). ▪ TMs will need to make available information that the traceability solution would need to associate with each tobacco item to

Stakeholder Option 4: Solution Requirements



Tobacco
Manufacturers
- continued

which a unique identifier (as part of the security feature) has been applied¹⁰⁶. The envisioned operational impact will further require either:

- Solution provider of the vision system providing a terminal / user interface for manufacturers operators to setup and capture information as part of shift setup (e.g. Intended market of retail sale); or
 - Provide an electronic interface for manufacturers to provide messages from their production systems to receive the required information electronically for the coding operations.
 - Equipment to read the barcode (EAN / GTIN) on the tobacco product unit as where part of an automated solution operated by the solution provider(s) to reference required master data to determine the product description, intended market of retail sale.
- TMs dispatch operations will be effected and require the unique serial numbers of the shipping items (at highest aggregation level) to be recorded when shipments are staged and /or loaded, with the same operational requirements identified as identified for Option 1. TMs will need to have on record the unique references numbers that identify customers and their storage facilities to which goods may be shipped (potentially using global supply chain standards such as GS1 GLN). Note: These dispatch operations would already be performed to some degree by those manufacturers with agreements with the EU, and will now need to be fulfilled by all tobacco manufacturers.
 - TMs must have exception processes in place, to record damaged or unsellable goods (various stages of aggregation).
 - As with Option 1, TMs will require business processes to support the submission of supporting commercial event data (invoice and payment records) to the data management providers.
 - TMs outside of the EU manufacturing for the EU market will need to implement a similar camera vision system, or other validation system,, with own solution components for aggregation recording and traceability information event submission.
 - This may require a mechanism for the EU commission to review of the tobacco traceability solutions that may be implemented in other non-EU countries, and the degree to which this meet the requirements for products placed onto the EU internal market;
 - While the combined unique identifier and security feature can readily be shipped to these remote locations, it may be necessary for the solution provider(s) to install and maintain the required vision systems in these locations.
 - **Note:** Countries outside the EU that intend to export

¹⁰⁶ See footnote 37 on page 48 above.

Stakeholder Option 4: Solution Requirements

Tobacco
Manufacturers
- continued

tobacco products to the EU will have to comply with EU legislation. It is recognised that beyond this scope, EU traceability requirements cannot be imposed on manufacturers of tobacco product in countries outside the EU that do not intend to import to the EU. In the case these products are brought illegally onto the EU internal market, there remains the need for internationally agreed standards as a traceability minimum, by preference agreed under the FCTC protocol.

- As with Option 2, it is anticipated that marking of products (at unit level) on arrival in the EU territory would in most cases not be feasible because of the extensive resulting damage to packaging, except in the cases of small volumes / specialised tobacco products

In addition, TMs:

- Will be required to source and operate a mechanism for application of the combined security feature and unique identifier on their production line. Where combined with the Member State tax stamp requirements, it is anticipated this will have limited additional impact on most manufacturers with tax stamp applicators already fitted on most production lines producing for the EU market.
 - Exceptions will be those markets not requiring tax stamps (approximately 20% of tobacco market)
 - Other tobacco products that may not require tax stamps (e.g. chewing tobacco).
- TM will be responsible for sourcing and implementing equipment for labelling cartons / bundles, mastercases and pallets, and recording aggregation events for each of these.
- TMs will be responsible for maintenance and upkeep of stamp applicators and equipment for the recording of aggregation events (whether self or agreements with OEMs) and required operation consumables.

For the operation of the vision system, or other validation system, by the solution provider:

- TMs will need to accommodate within reason, representatives of the solution provider being allowed access to production areas for the purposes of operation, maintenance and support of the camera vision system, or other validation system.
- TMs may be requested to make available a space that can be secured and locked, suitable for the installation of server and communication equipment operated by the solution provider, as well as network connectivity from the allocated server room to the production lines.
- TMs are responsible for operation and maintenance of network connectivity at each production site, for use by the solution provider systems.
- TMs advise solution provider(s) of maintenance schedules (to

Stakeholder Option 4: Solution Requirements

Tobacco
Manufacturers
- continued

optimise tobacco traceability solution maintenance times and minimise impact on manufacturers).

TECHNICAL

- As in Options 1,2 and 3, extensions to current TMs financial accounting systems will be required to export commercial transaction information including invoice, order number, and payment records:
 - The solution provider(s) application will use this information to link the unique identifiers of the pallets, mastercases and/or cartons during the order dispatch process.
 - It is anticipated that the extent of commercial data to be exported may have significant implications, and these are discussed further in 8.6.9 below.
- TMs install and operate required equipment for aggregation recording equipment (pack through to pallet).
- TMs must ensure integrity of aggregation events, aggregation stations for pack-to-carton and carton-to-mastercase should include physical and logic safeguards such as shields, covers, doors (including cabinet open / close sensors) to prevent potential interference or tampering (intentional or unintentional) that may affect the certainty of recording the correct child items with the associated parent container.
- Depending on solution implementation method, system interface to advise solution provider system of related production information (e.g. intended market, product type).
- Site network connectivity and power supply to support solution provider(s) on-site equipment)

POTENTIAL LEGISLATIVE CONSIDERATIONS FOR EU AND MEMBER STATES IN RELATION TO MANUFACTURERS

- Legal basis required for fitment of tobacco traceability components on manufacturers production lines.
- Requirements to keep and record tobacco production, sale and movement data (for supporting verification and audit purposes)
- Policy in place for Member State / EU agency sign-off of manufacturers implementation (operational readiness assessment)
- Consideration of remedial measures, penalties, sanctions or potential legislative actions against manufacturers by EU and Member State authorities where non-compliance is identified.



SME
Manufacturers

It is anticipated that Option 4 would provide reduced impact on Small and Medium Enterprise (SME) manufacturers and producers of other tobacco products, as compared to Options 1, 2 and 3.

- SMEs would apply the combined security feature using either

Stakeholder Option 4: Solution Requirements

SME
Manufacturers
- continued

automated or manual methods.

- The camera vision system, or other validation system, operated by the solution provider may either be installed on line, or provided as a handheld / mobile device depending on the level of automation on the line.
- SMEs using consumer invoicing and accounting software with little opportunity for extension and customisation may use a stand-alone system provided by the solution provider for the capture of information required for tobacco traceability purposes.
 - As with Option 1, duplicate capturing activities will have an operational impact of additional time required for the capture of information into the traceability system.
- As in Option 1 and 2 above, SMEs may use handheld devices capable of reading the machine-readable unique identifier on unit packets of tobacco, and to support manual aggregation processes, where a further operational impact is envisaged in the additional time required to scan each item during packing operations.



Solution
Provider

OPERATIONAL

- Solution Providers (SPs) will be responsible for implementing equipment on each production line for verifying the presence of the security feature, and reading the unique identifier.
- SPs will be responsible for maintenance and upkeep of their tobacco traceability related equipment and required operation consumables.
- As in Option 2, SPs will be required to provide support to tobacco manufacturers and distribution chain operators where necessary
- To minimise impact on manufacturers, mechanism should be in place for SPs to monitor all operating sites to ensure tobacco traceability equipment is operating within acceptable parameters, action operational alerts, schedule required and preventative maintenance.
- SPs provide support to EU and Member State authorities:
 - Provide query management tool and interface for authorised parties to access tobacco traceability data.
 - Assist with information requirements for audit, inspection and enforcement activities.

TECHNICAL

- SPs transmit data to data management providers in agreed form (e.g. GS1 EPCIS standard with agreed extensions to accommodate TPD Article 15 data elements).
- As in Option 2, it is recommended that SPs:
 - Provide that all solution components and cabinets be

Stakeholder	Option 4: Solution Requirements
 <p data-bbox="229 356 363 450">Solution Provider - continued</p>	<p data-bbox="603 280 1278 311">protected against access by unauthorised parties.</p> <ul style="list-style-type: none"> <li data-bbox="555 327 1358 421">○ Provide handheld scanners / reading devices for small manufacturers and distribution chain operators to meet tobacco traceability requirements <li data-bbox="555 436 1358 562">○ Develop and maintain a tobacco traceability query application that may be operated by EU and Member State authorities to support query, inspection and audit functions <li data-bbox="555 577 1390 734">○ Provide a system interface for EU and Member State authorities to access traceability data for analysis, as well as business intelligence and reporting tools to provide oversight of the tobacco manufacture and distribution chain. <ul style="list-style-type: none"> <li data-bbox="459 750 1394 875">▪ SPs adhere to strict confidentiality requirements to protect information on tobacco manufacturers' production, production capacity (planned or actual) with parties other than authorised EU and Member State authorities. <p data-bbox="411 913 1310 976">POTENTIAL LEGISLATIVE CONSIDERATIONS FOR EU AND MEMBER STATES IN RELATION TO SOLUTION PROVIDER(S)</p> <ul style="list-style-type: none"> <li data-bbox="459 996 1394 1279">▪ Information and record keeping requirements for SPs to maintain: <ul style="list-style-type: none"> <li data-bbox="555 1077 1337 1171">○ Records on system operation including items counted, items with security feature and unique identifiers successfully read <li data-bbox="555 1187 1390 1279">○ Regular information verification activities (including reconciliations) to ensure the tobacco traceability solution is operating correctly. <li data-bbox="459 1294 1394 1357">▪ Standard service provider contract management considerations related to the solution provider(s)
 <p data-bbox="229 1485 344 1579">Security Feature Provider</p>	<ul style="list-style-type: none"> <li data-bbox="459 1400 1382 1693">▪ The appointed security feature provider will be required to add a unique identifier to each label / stamp, with quality control to verify the readability of each machine-readable code (compliance with the specification for the agreed symbology, as well as relevant quality measure standards, such as ISO/IEC15415:2011 - Automatic identification and data capture techniques -- Bar code symbol print quality test specification 2D symbols or related AIM DPM [used for data matrices] or equivalent) <li data-bbox="459 1709 1358 1803">▪ It is proposed that the EU consider allocating a unique prefix solution provider, with the requirement that this be prepended to the generated unique identifier¹⁰⁷. <li data-bbox="459 1818 1382 1881">▪ Applied unique identifiers on security feature labels / stamps are recorded to provide a control mechanism of security features



Solution Provider
- continued

protected against access by unauthorised parties.

- Provide handheld scanners / reading devices for small manufacturers and distribution chain operators to meet tobacco traceability requirements
 - Develop and maintain a tobacco traceability query application that may be operated by EU and Member State authorities to support query, inspection and audit functions
 - Provide a system interface for EU and Member State authorities to access traceability data for analysis, as well as business intelligence and reporting tools to provide oversight of the tobacco manufacture and distribution chain.
- SPs adhere to strict confidentiality requirements to protect information on tobacco manufacturers' production, production capacity (planned or actual) with parties other than authorised EU and Member State authorities.

POTENTIAL LEGISLATIVE CONSIDERATIONS FOR EU AND MEMBER STATES IN RELATION TO SOLUTION PROVIDER(S)




- Information and record keeping requirements for SPs to maintain:
 - Records on system operation including items counted, items with security feature and unique identifiers successfully read
 - Regular information verification activities (including reconciliations) to ensure the tobacco traceability solution is operating correctly.
- Standard service provider contract management considerations related to the solution provider(s)





Security Feature Provider

- The appointed security feature provider will be required to add a unique identifier to each label / stamp, with quality control to verify the readability of each machine-readable code (compliance with the specification for the agreed symbology, as well as relevant quality measure standards, such as ISO/IEC15415:2011 - Automatic identification and data capture techniques -- Bar code symbol print quality test specification 2D symbols or related AIM DPM [used for data matrices] or equivalent)
- It is proposed that the EU consider allocating a unique prefix solution provider, with the requirement that this be prepended to the generated unique identifier¹⁰⁷.
- Applied unique identifiers on security feature labels / stamps are recorded to provide a control mechanism of security features

¹⁰⁷ For further consideration of ensuring identifies for items are unique see ISO 15459 (1-8) -- Information technology – Unique identifiers

Stakeholder	Option 4: Solution Requirements
 <p>Security Feature Provider - continued</p>	<p>produced.</p> <ul style="list-style-type: none"> ▪ Security features are shipped to tobacco manufacturers, with the unique identifier providing a mechanism to track these dispatch and receipt movements.
 <p>Distribution Chain Operators</p>	<ul style="list-style-type: none"> ▪ It is anticipated that the same operational, technical and legal implications and requirements apply for Option 4 as envisaged in Options 1, 2 and 3. ▪ Further, to accommodate the number of different data management providers (as considered under option 1, 3 and 4), a discovery service will be required, which will apply the predefined business logic to route submitted distribution chain events to the relevant Member State repository.
 <p>Data Management Provider(s)</p>	<p>OPERATIONAL</p> <ul style="list-style-type: none"> ▪ Data Management Providers (DMPs) provide data hosting service in the Union in line with contracts concluded with the respective Member State ▪ As in Option 1 and 2, the DMPs will be required to: <ul style="list-style-type: none"> ○ Administer user rights and security access. ○ Provide a pilot / test environment for use by solution provider(s) and distribution chain operators to test system changes and enhancements. ○ Maintain audit logs that record access and activity related to all accounts. ▪ DMPs provide access to external auditors as necessary for their purpose to monitor activities related to the Data Management Providers <p>TECHNICAL</p> <ul style="list-style-type: none"> ▪ DMPs are required to use an EU-wide standard that enables the correct repository to be identified in order to determine the correct destination for a traceability event message. Further, for multiple data management providers it is recommended that a discovery service be implemented to route traceability events and queries to the appropriate event repository. ▪ As in Option 1, 2 and 3, DMPs will need to: <ul style="list-style-type: none"> ○ Implement support for industry standards for information exchange, such as EPCIS for traceability events, and EDI formats for receiving of commercial documents (invoice, order and payment records).

Stakeholder	Option 4: Solution Requirements
 <p>Data Management Provider(s) - continued</p>	<ul style="list-style-type: none"> ○ Implement a robust security model controlling which parties may update records, specifically with controls to prevent amendments and changes to existing records by tobacco manufacturers and distribution chain operators. ○ Provide an interface for authorised EU and Member State authorities to export tobacco traceability events to another repository for analysis ○ Implement secure data transmission and encryption techniques to be used for all received and transmitted data. <p>POTENTIAL LEGISLATIVE CONSIDERATIONS FOR EU AND MEMBER STATES IN RELATION TO DATA MANAGEMENT PROVIDERS</p> <ul style="list-style-type: none"> ▪ DMPs must adhere to data storage confidentiality requirements for each Member State, duration of storage, tiered storage, access control, back-ups, business continuity and disaster recovery. ▪ DMPs agreements should include SLAs specifying availability and performance requirements. ▪ Standard service provider contract management considerations related to the data management provider(s)
 <p>Member State Authorities</p>	<p>OPERATIONAL</p> <ul style="list-style-type: none"> ▪ Member State Authorities (MSs) are responsible for appointing a tobacco traceability solution provider at point of tobacco manufacture: <ul style="list-style-type: none"> ○ Operation of bid and selection processes. ○ Develop a review period and framework for conducting a basic audit of solution provider(s) activities: <ul style="list-style-type: none"> ▪ Performance against SLA's and KPI's monitoring. ▪ Audit of tobacco traceability information (sampling of items to validate recorded information) to validate integrity of solution. ○ Consideration should be given to consolidating Member State traceability solution requirements at production source (See 8.6.4 below) ▪ MSs are responsible for identifying a data management provider to provide a repository for tobacco traceability events relevant to the Member State. <ul style="list-style-type: none"> ○ Operation of bid and selection process. ○ Contract management of service provider for suggested consideration, see section 10 below. ▪ MSs are given access to tobacco traceability data to support authorities' monitoring, reporting, surveillance and enforcement

Stakeholder Option 4: Solution Requirements

Member State
Authorities
- continued

activities.

- MSs must conduct regular market surveillance campaigns to verify compliance of EU manufactured products and assess levels of illicit items on the internal market.
- MSs operate a solution for query and analysis of tobacco traceability data. Development of solution either by Member State, or solution provider. Access to tobacco traceability data is used to support Member State authorities' monitoring, reporting, surveillance and enforcement activities.
- MSs party to the WHO FCTC Protocol may wish to utilise access to tobacco traceability data for the purposes of responding to enquiries received through the global information-sharing focal point.
- Stakeholder education and consumer-awareness campaign activities related to introduction of tobacco traceability solution (and logically these activities may be combined with activities to promote consumer education of security feature).

TECHNICAL

- MSs should be able to access tobacco traceability data through either:
 - Query Tool developed by Member State, or by Member State solution Provider(s); or
 - A technical interface provided by the data management provider for exporting tobacco traceability data to a Member State authority operated repository.
 - A business intelligence and reporting tool provided by the provider(s) to ensure oversight of the tobacco distribution chain (at Member State level), including alerts and reports to support / aid Member State authorities current state supervision controls.




POTENTIAL LEGISLATIVE IMPLICATIONS

Similar requirements as for Option 3 are envisaged:

- MSs must have authority and a legal basis to access tobacco manufacturer and distribution chain operator compliance.
- MSs should consider legal basis and sanctions to enforce requirement for marking with security feature, secondary unit marking (e.g. carton), master case marking and pallet marking, together with aggregation events.
- MSs should consider legislation to enable submitted tobacco traceability data to be used by other EU agencies, national agencies / departments where a benefit of national interest can be demonstrated.

In addition:

- Prohibit tampering, adjustment and movement of Solution

Stakeholder	Option 4: Solution Requirements
 Member State Authorities - continued	Provider's equipment without prior notification and approval.
 EU Authorities	The same requirements are envisaged for the EU authorities as those identified in Option 3b.
 Consumers	It is not expected that there are any material implications resulting from Option 4 that will impact consumers.

8.5.4 KEY CONSIDERATIONS

- Compatibility is required between location of the security feature on each of tobacco product, and the aggregation recording solution
- From Article 16 §1 of the TPD it is understood that tobacco products produced within the EU for export do not require a security feature. Because option 4 integrates the security feature with the unique identifier, the implication is that tobacco products manufactured for export (and therefore not requiring a security feature) would require an alternative mechanism for the unique identifier to be applied to the product.
 - Therefore an alternative method for affixing the unique identifier, or a direct marking solution as described in option 1, 2 or 3 would need to be considered for those production lines producing for the export market (extra EU-28). This means that the cost synergies for option four only apply to manufactured products for the EU market.
 - However, the parallel introduction of two separate mechanisms, i.e. one for intra-EU sales and another for exports, may lead to operational inefficiencies and additional costs. The co-existence of the two mechanisms must be also considered in terms of potential risks for the overall functioning of the traceability system. Given these considerations, it cannot be excluded that the most efficient solution could be to apply security features to all production, including exports.
- An analysis, including a security audit of existing solution provider applications (code generator, line software, ERP systems etc.) for the creation and recording of serialised marks was not in scope for this feasibility study. While general mechanisms should be implemented to ensure the correct operation of the traceability solution, the scope for a largely automated control may include the reconciliation of summary traceability data recorded by the independent solution provider against the declarations for excise tax purposes made by the tobacco manufacturers. Further, a reconciliation with an additional data source may include the volumes of security feature elements used, and where in operation in a member state, the volumes of tax stamps used.

8.5.5 CONSIDERATIONS IN THE CONTEXT OF THE WHO FCTC PROTOCOL

It is anticipated that Option 4 could be implemented in a manner compatible with the WHO FCTC Protocol. Consideration would need to be given to paragraph 4.2 of article 8, which states that the date of manufacture shall form part of the unique identifiers. For Option 4, it is proposed that the unique identifier as contemplated in Article 15 of the TPD would be printed on the security feature itself, and at that time the date of application to the tobacco products would not be known.

Therefore, compatibility with this requirement of the protocol would need to consider:

- Acceptability of manufacture date being accessible by means of a link; or
- Requirement on manufacturers to include date of manufacture on tobacco items (considered as extension of expiry date and price information that is typically added). Then the inclusion of this printed date, the barcode (EAN / GTIN) and the identifier would be interpreted as the "Identification Markings" that collectively would meet the strict interpretation of 4.2

A direct marking solution (either as envisaged under Traceability Option 1, 2 or 3 above) would be required for tobacco products produced in the EU for export as TPD Article 16 §1 only requires security features to be applied to tobacco products placed on the EU market

8.5.6 ADVANTAGES AND DISADVANTAGES

Advantages	Disadvantages
<ul style="list-style-type: none"> ▪ EU Government and Member State oversight and independence of tobacco traceability solution at point of manufacturer. ▪ Synergies with secure label reduce the amount of equipment implemented and operated on production lines. ▪ Significantly reduces risk of traceability solution causing potential production downtime because no need for code generation and marking on production line. ▪ Traceability elements embedded in the Security Feature allows inventory control and tracking of security feature items themselves prior to application onto tobacco packs. ▪ Minimises impact on distribution chain operators that benefit from flexibility and choice in terms of commercial technologies and solutions. ▪ Ability for Member States to reconcile independent data at point of manufacture with manufacturer aggregation data and distribution chain data to monitor compliance. 	<ul style="list-style-type: none"> ▪ Compatibility requirements in terms of placement of the security feature on the tobacco item and downstream aggregation processes. ▪ Online connectivity required to access all traceability information during field inspections - only basic information can be decoded from unique identifier in offline scenarios. ▪ Solution has very high dependence on interoperability amongst numerous providers and data integration across multiple sources. ▪ Risk of incompatibility and data integration issues during initial implementation. ▪ Integration of Member State level solutions required to provide EU-level oversight and tools for EU Agencies. ▪ Potential system performance disadvantages when conducting tracing queries that span multiple Member State repositories. ▪ Direct Marking solution required for marking tobacco products produced for export (as these would otherwise not require application of a security feature already containing the unique identifier). In context – products manufactured for export represent < 7% of the EU tobacco market.

8.5.7 COMPATIBILITY WITH SOLUTION CRITICAL SUCCESS FACTORS

A summary review of traceability option 4 against the critical success factors identified as part of the problem statement is presented below.

1	Ensure each pack is marked with a unique identifier (Article 15, §1);	☑
2	Provide an accurate mechanism for recording the movement (tracking) of tobacco products through the point of manufacture to the last economic operator before retail (Article 15, §5);	☑
3	Support the concept of aggregation (Article 15, §5);	☑
4	Store data independently (not by the tobacco industry) (Article 15, §8 and recital 31);	☑
6	Ensure that the systems used for the unique identifier and the related functions are fully compatible with each other across the European Union (Article 15, §11b);	☑

7	Protect confidentiality and safeguard that decoding and full access to the data storage facilities limited to authorised authorities and only exceptionally in duly justified cases to tobacco industry under restrictive conditions (article 15, §8)	☑
8	Be compatible with current tobacco production, packaging and the trade environment to minimise the impact on tobacco production taking into consideration production speeds, equipment, etc. (internal market proportionality obligations);	☑
9	Uphold respect for data protection as specified in the EU legal framework (Directive 95/46/EC) (Article 15, §10);	☑
10	Be resistant to manipulation. This includes physical measures such as providing that marks are irremovable and indelible, but also solution design considerations such as non-predictability of unique identifier codes, traceability data reconciliation against other data sources, safeguards against traceability being accessed / used by unauthorised parties; (Article 15, §1)	☑
11	Enable Member States and EU authorities to monitor and survey the market as per respective mandates. (general aim of Article 15 and recital 29);	☑
12	Solution components currently being used in a commercial supply chain environment and avoid unnecessary burden for business and/or authorities (Impact assessment considerations).	☑

Table 35 –Summary assessment of Traceability Option 4 Against Solution Critical Success Factors

8.6 FURTHER CONSIDERATIONS ACROSS ALL FOUR OPTIONS

Across the four traceability options there are several aspects of the traceability solutions that may warrant further consideration by the EU Project team and EU Member States. Each of these are discussed in the following section.

8.6.1 EU STANDARDS FOR THE SIZE AND LOCATION ON TOBACCO ITEMS

It is recommended that EU standards allow flexibility in the choice of location for the unique identifier on the tobacco items. This will accommodate variations in manufacturing processes that may affect which areas of the item are accessible (e.g. bottom or lower sides of packs may be preferable given the orientation of the packs at that point on the production line after packing but before the overwrap is applied, orientation or rotation of tins, etc.). Further, the manufacturers will, where applicable, also need to consider locations that are compatible with the aggregation processes that are used.

However, it would be relevant to specify the minimum sizes (for readability) and requirement for the unique identifier to remain intact after product opening. For cigarette packs, direct application of the unique identifier directly to the pack will ensure the mark is irremovable and placement under the clear wrap will offer some protection of the mark during packing and transportation operations.

8.6.2 DATA ELEMENTS FORMING PART OF THE UNIQUE IDENTIFIER

The TPD requires each tobacco unit to be marked with a **unique identifier** that will record associated traceability information that could assist government authorities in

combating illicit trade¹⁰⁸. Across the four options, the project has identified 3 feasibility considerations related to the unique identifier:

- The potential size of the unique identifier given the number of data elements to potentially be included as part of the unique identifier itself (in addition to the base requirement of ensuring uniqueness);
- Data elements required to create the unique identifier that may not be known to the manufacturer at the time of manufacturing; and
- Interpretation of “manufacturer” in the context of production processes currently used in the domain of other tobacco products.

The TPD specifies several data elements that need to be recorded. These are largely the same or extend further than those items identified in 4.1 of Article 8 of the WHO FCTC protocol.

WHO FCTC Protocol	Tobacco Products Directive – Article 15
» (a) date and location of manufacture	» (a) the date and place of manufacturing
» (b) manufacturing facility	» (b) the manufacturing facility
(c) machine used to manufacture the tobacco products;	» (c) the machine used to manufacture the tobacco products
(d) production shift or time of manufacture	» (d) the production shift or time of manufacture
the name, invoice, order number and payment records of (e) the first customer who is not affiliated with the manufacturer	(k) the invoice, order number and payment records of all purchasers from manufacturing to the first retail outlet
» (f) The intended market of retail sale	» (f) the intended market of retail sale
» (g) Product description	» (e) the product description
(h) Any warehousing or shipping	
(i) The identify of any known subsequent purchaser	(j) the identity of all purchasers from manufacturing to the first retail outlet
(j) The intended shipment route, the shipment date, shipment destination point of departure and consignee	» (g) the intended shipment route
	» (h) where applicable, the importer into the Union
» Shall form part of the unique identifier	(i) the actual shipment route from manufacturing to the first retail outlet, including all warehouses used <i>as well as the shipment date, shipment destination, point of departure and consignee</i>

Table 36 - Comparison of Information Requirements Between WHO FCTC Protocol Article 8 and TPD Article 15

Some traceability systems apply a simple unique identifier to each item, such as a serial code, with the express purpose of distinctly identifying each item. In this case, the only requirement is that the identifier ensures each item is unique, and that the generated codes are not predictable. Associated manufacturing and distribution data is then stored in a database and referenced to the unique identifier. As a result, the data of the unique identifier itself is relatively small and requires limited information to be encoded onto the unit for track and trace purposes.

The TPD, however, is specific that items (a) to (g), and where applicable (h), should *form part of the unique identifier* itself. These items also extend the number items from those identified in 4.2 of Article 8 of the WHO FCTC Protocol considerably (see comparison

¹⁰⁸ See footnote 37 on page 47 above.

table above). Compared to accessing information by accessing records in a data repository associated with that unique identifier, embedding these in the code itself means that decoding and retrieving this data can be done in an environment without internet or network connectivity.

However, this additional data to be stored increases the size of the unique identifier, proportional to the quantity and detail of the additional data. As the size of the unique identifier itself increases, so the size of the machine-readable code increases (such as a barcode, data matrix, ISS Dotcode). This becomes especially relevant when considering the constraints of direct marking of these machine readable codes onto units of tobacco products on very high-speed production lines. A barcodes data capacity is a function of its physical size, and the physical size has implications for the printing / marking equipment that applies the bar code. As the production line speed increases, the available time to print the barcode decreases, together factors such as vibration and movement creating a technical challenge to reliably apply machine-readable codes with high degree of reliability¹⁰⁹.

Implementations of direct marking solutions at high speed are in successful operation on tobacco lines operating at 1,000 packs per minute, and beverage lines operating at 2,400 items per minute, with very high readability rates of over 99%. However, in these scenarios, the unique identifier comprised less than 16 alphanumeric characters of information, and its anticipated that even triple this volume would be insufficient for embedding all of the data elements considered in Article 15 §3 as part of the unique identifier itself and would be prohibitively costly given the constraint of current technologies available. To clarify, the technical constraints do not make achieving the requirement impossible, but the feasibility consideration being raised is the implication of additional data elements necessitate increasingly sophisticated technology and equipment (and evidenced in the significant cost differences identified between high and medium speed production lines in Section 11 below).

Therefore, the following considerations are proposed to address the feasibility concerns related to the data size and potential limitations in data elements known at the time of tobacco manufacture:

- In the unique identifier, combining similar or related elements, for example:
 - Recording the date and time of manufacture to at least second level, meeting the requirements for both (a) and (d)
 - Assigning a unique reference number to each manufacturing line in the EU, and therefore from one code, location in (a), (b) and (c) can be determined.
- Consider that information in the retail (EAN / UPC) barcode (with GTIN) could be used as the basis to derive the product description and intended market of sale (with the implication that at time of tracing, both barcodes would potentially need to be scanned).

¹⁰⁹ The constraint is a function of both the size of the barcode, and the speed capabilities of the printer. Consider a scenario of a cigarette production line operating at 1,000 packs per minute – it is not only a matter of a printer being able to print 1,000 barcodes per minute (60 milliseconds per barcode) – but also that the available printing / marking opportunity to print is limited to a fraction of this: Barcodes require quiet zones around the borders, together with tolerances around the area to accommodate movement, vibration, shifts in the alignment of the item on the line, further space between the packs on the line (often required for sensors to detect the individual packs). Therefore, as an illustrative scenario, printing/marking a 6mm square barcode onto the 22.5mm side of a tobacco pack in the scenario of a 1,000 pack per minute line, and using illustrative spacing on the line between packs of 10mm, in reality the printer / marking device would only have 11 milliseconds to apply each barcode. In other words, the printing / marking device needs to be capable of applying an equivalent of over 5,400 6mm continuous barcodes per minute (if they were arranged side to side) to meet the performance marking requirements of a 1,000 packs per minute tobacco line.

- Potentially consider increasing the scope of items that are included as linked data in the repository, such as item (g) which could be a larger data item. While not part of the unique identifier marking on the product, time of submission requirements could still be imposed, e.g. intended shipment route must be submitted prior to first dispatch of the consignment.

The third feasibility concern relates to a frequently occurring business practice where tobacco products are manufactured and placed in non-market specific retail packaging. These products are produced in batches to full stock, and could remain in stock for several months until an order is received. At the time of order, the products are retrieved from stock, and prepared for the intended market at a finishing station where health warnings, tax stamps (or fiscal markings) and the barcode (EAN / UPC) for the relevant market is then applied. Therefore, at the time of manufacture of the tobacco product (when time, location and line is known), the other data elements related to intended market and intended shipment route would not be known.

An alternative consideration may therefore be to consider for these other tobacco products, **that the unique identifier be applied at the time of finishing and preparation for the intended market.** Therefore, the unique identifier would be placed on the product at the same time as the other elements (health warning, barcode). For option 4, the unique identifier would be applied simultaneously through the combined security feature element (and where applicable and elected by the Member State, combined with the tax stamp / fiscal marking).

Once the considerations above have been reviewed, a data lifecycle model can be defined. This would include considering the size of the unique identifier (number of alphanumeric characters), the number of unique identifiers to be supported at one time, and "spaces" to ensure a likelihood of randomly guessing a legitimate code and rules governing the reuse of unique IDs after a certain time. The EFPIA developed guidelines for coding (including information related to unique identifiers) of pharmaceutical products in the EU for traceability purposes makes some recommendations for these elements (such as probability for guessing a legitimate code should be less than 1 in 10,000)¹¹⁰.

8.6.3 SECURITY AND ENCRYPTION OF THE UNIQUE IDENTIFIERS

To improve the security of the traceability system, it is recommended that unique identifiers placed on tobacco units are encrypted. This provides a mechanism to hinder potential fraudsters from predicting or being able to guess (with some probability of success) valid unique identifiers to be placed on tobacco products.

Encryption is a concept where a string of data – such as a composite of the data elements of the unique identifier – is processed using an encryption algorithm using a key / password to convert the data into an encrypted-coded string. This encrypted-coded string bears no resemblance to the original unencrypted string and the original data elements cannot be determined by any part unless they are able to successfully decrypt the coded string.

¹¹⁰ European Medicines Verification System (EMVS) - European Pack Coding Guidelines, Version 3.6, June 2013.

SYMMETRIC ENCRYPTION

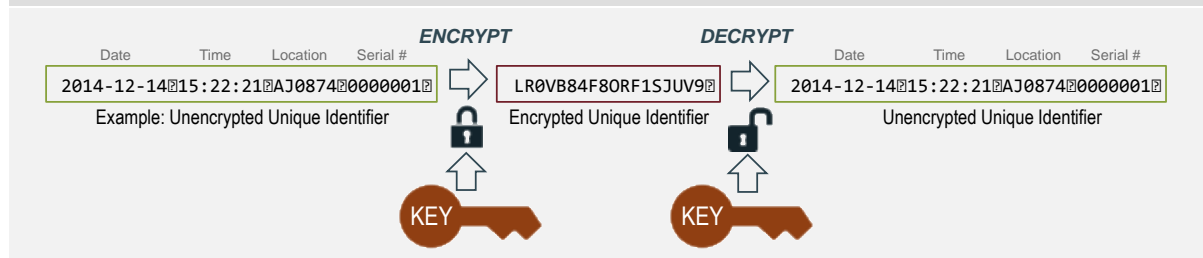


Figure 44 - Illustration of a Symmetric Encryption Process Using a Single Key

In the case of symmetric encryption, **the same key** that is used during the encryption process also serves as the input in the decryption process. As shown in Figure 44 above, an illustrative example of an unencrypted unique identifier is shown as a composite of several data elements that may include the date, time, location and serial number of a particular product being marked. Using an encryption key, this unique identifier is converted into an 18 character unique identifier. The same key is able to decrypt this coded element to determine the unencrypted unique identifier (and as a result, the data elements of which it was composed).

ASYMMETRIC ENCRYPTION

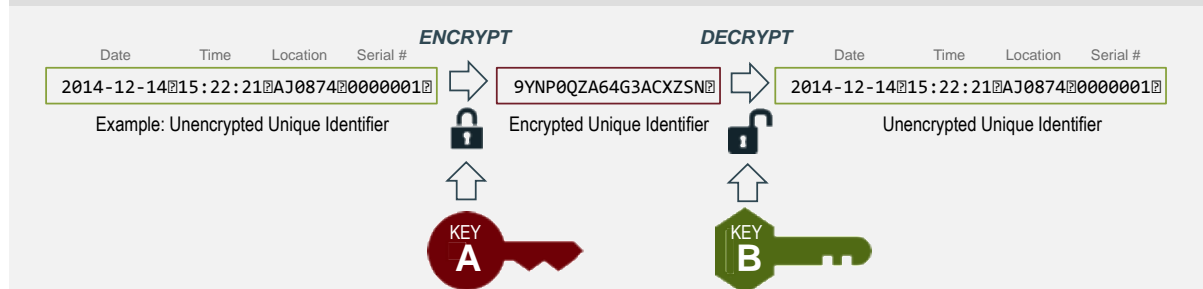


Figure 45 - Illustration of an Asymmetric Encryption Process using two related keys (public / private keys)

In the case of asymmetric encryption – **two different keys are used for the encryption / decryption processes** as illustrated in Figure 45 above. The keys are mathematically linked when the pair is created, but after the fact, there is no immediate method for a party in possession of one key to determine the other key. This provides an additional element of security to a solution where one of the keys may be retained by a controlled group of parties (a private key), while the other may be shared with a larger group (public key).

As an illustrative example, consider in the context of a traceability solution that the private key (Key A) is controlled by the party generating the unique identifiers and is used to encrypt the unique identifier at the time it is printed. The second key (Key B) might then be shared with those parties with the authority to conduct traceability queries and would allow the encrypted unique identifier to be decrypted and possibly the underlying data elements to be determined.

The benefit of asymmetric encryption is that Key B can be shared with multiple parties (an act that increases potential risk that the key may be compromised) with the assurance that should Key B be compromised, it would still not enable the illicit operators to generate new encrypted unique identifiers (as this would require Key A which has not been shared).

Encryption of the unique identifier may provide an additional security advantage in the context of a traceability system. By storing the unencrypted unique identifier in the traceability data repository, it provides a safeguard should the traceability data be

compromised during transmission or at the data storage site. In the event of this, the illicit operators would not be able to generate valid encrypted unique identifiers without further having access to the encryption key (Key A). While asymmetric encryption requires additional system processing, as compared to symmetric encryption¹¹¹, it is arguable that this is warranted, given the additional solution security it provides.

As a good security practice, the pair of keys should be changed regularly (annually) to safeguard against the possibility that computational brute force is used to determine the keys used. Because of the size of the keys, it's anticipated that such a brute force attack would take so long to determine the keys used that by the time it was completed, different keys would be in operation.

Note:

- The encryption algorithms can be used to hinder fraudsters from generating new unique identifiers, or should a database of traceability data (including aggregation) be compromised, from generating the encrypted unique identifiers that may appear on those tobacco packs. However, irrespective of the level of encryption applied, it provides no safeguards against the encrypted unique identifiers applied to legitimate tobacco products being read and then being copied onto illicit packs. To perpetuate this fraud, the illicit operators would need to have access to legitimate tobacco products (and potentially with the aggregation hierarchy of pack-to-carton and carton-to-mastercase intact, in order to record and reproduce the encrypted markings on each.
- The strength of the security feature and its ability to resist counterfeiting and duplication, provides a potential safeguard against replication of encrypted unique identifiers onto illicit packs. These security elements are discussed further in section 9 below.

8.6.4 CONSOLIDATING MEMBER STATE REQUIREMENTS AT PRODUCTION SOURCE

Both option 3 and option 4 propose Member States appoint solution providers to operate specific elements of the traceability solution. To operate the solution in these member states, these solution providers may be required to install equipment on production lines, and different solutions may therefore be operating across the EU-28.

It is recommended that Member States require that these solutions apply to all tobacco products **manufactured** in their territory only, and not require that this same solution have to be used for tobacco manufacturers in other EU Member States and sold in their territory. This will, therefore, require Member States to accept tobacco products into their territory that may have been manufactured in another Member State where potentially a different solution provider has been appointed and operates the traceability solution for products marked in that territory.

The agreement between Member States to allow this compatibility prevents a scenario where a tobacco production line producing for multiple Member States needs to be outfitted with equipment from multiple solution providers, where at any one point time only one of these is active. The scenario of specific prefixes assigned to each solution provider (as considered in 8.3 above) ensures that unique identifiers remain unique across Member States and support an interoperable traceability solution across the EU.

This recommendation would apply to the tobacco traceability requirements only (for the efficiency reasons described above), and separate of the other Member State

¹¹¹ <http://resources.infosecinstitute.com/symmetric-asymmetric-encryption/>

requirements applicable to all tobacco products sold in their territory (both domestically manufactured, manufactured in another EU Member State, or manufactured outside the EU). This would include health warnings in the relevant language, and tax stamps for the market of destination, irrespective of the market of production.

8.6.5 DISTRIBUTION CHAIN READINESS

It is anticipated that the requirements of Article 15 will significantly impact the distribution chain economic operators' processes. Feedback from a distributor / wholesaler industry association indicated that less than approximately 60% of these economic operators are using electronic systems for recording the receipt and dispatch of consignments.

Whilst arguably the tobacco traceability requirements are a natural extension of existing warehouse receipt and dispatching processes, it is anticipated that, of those operating electronic systems, few of these existing processes and systems record information required for traceability purposes. In other words, at the time of receipt, a distributor's warehouse management system may record the entry of master cases of a particular product into inventory, and increment the inventory counts accordingly – but not record the identifiers of the specific master case containers themselves.

Initial feedback indicates that currently there are generally low levels of system integration and use of industry standards for the electronic exchange of commercial information between manufacturers, distributors and wholesalers. Generally, purchasing relationships are well established and daily transaction volumes have not warranted investment in electronic procurement and electronic information exchange platforms.

It is therefore expected that initially, the majority of tobacco traceability events will be recorded using independent devices. This lack of system integration may require the dispatch operators to recapture information such as customer and address information with an adverse process time impact on these operators. For the larger distribution chain operators, over time, there is likely to be a migration / integration of the required tobacco receipt / dispatch process into their Warehouse Management System (WMS) and Enterprise Resource Planning (ERP) information systems.

Finally, it is worth noting that the landscape of distributors involved with tobacco products in the EU spans a wide variety, from large, consolidated operators, to the model of highly fragmented small and medium operators. Most of these smaller operators do not deal exclusively with tobacco products, and it is therefore anticipated that introduction of tobacco traceability requirements will create some economic pressure to concentrate operators that do deal in tobacco. While TPD Article 15(7) takes into account that the compliance burden for distributors is at least partially shifted to manufactures, it is anticipated that beyond the investment in equipment for the operation of the traceability solution itself, that the operational impact on business processes to comply with requirements to record the receipt, movement and dispatch of tobacco products may result in some operators determining that the cost of the impact does not justify the revenue contributions of tobacco products in their distribution portfolio.

In light of these points, it is suggested that upon the ratification of the chosen solution for traceability and security features, the EU Commission conducts a survey of the distribution chain operators across Member States to determine their level of relative readiness based on the principles of the selected solution. A segmented and differentiated implementation approach may be considered for different categories of distribution chain operators (e.g. vending machine operators, cash & carry wholesalers and mobile sales forces). Further, based on the readiness, a phased implementation model could be adopted where the EU Commission define a staggered implementation date per stakeholder within the distribution chain.

8.6.6 REGULATING COMPLIANCE IN THE DISTRIBUTION CHAIN

It is a practical reality that discrepancies, mistakes and clerical errors are going to occur in both the commercial flows and physical good flows in the distribution chain. Commercial processes, such as credit notes and stock returns, are evidence that these erroneous events happen, and need to be corrected as and when they are discovered.

In the operation of the tobacco traceability solution, these same discrepancies will occur, and similarly may result in discrepancies and alerts regarding the integrity of the traceability data. It should therefore be a consideration by the EU and Member State authorities to what degree the manufacturers and distribution economic operators are responsible for reconciling discrepancies in traceability events between themselves, or whether follow up activities will be conducted, after the fact, by the authorities themselves.

In an operating model where manufacturers and distribution economic operators are only responsible for recording and submitting traceability events when tobacco products are received, stored, and then dispatched to the next party – there exists the possibility that potential discrepancies between what the sending party reports as sent and what the receiving party reports as received would not be apparent to the parties (as their responsibilities are only to record and report their own activities).

Therefore, the project team may wish to consider the degree to which the traceability solution attempts to manage the integrity of the traceability data:

- 1) In the passive model described above, there may be no further obligation on the parties other than to report their own receipts and dispatches. The solution would have two corrective elements in the form of (1) the existing commercial controls, such as order receipt and checking processes and stock counts, and (2) the potential for Member State authorities to draw exception reports and alerts from the traceability solution for investigation and follow-up (volume discrepancies between parties and out-of-sequence events such as a Mastercase being dispatched to two different parties, missing aggregation / disaggregation steps, etc.). These reports may be drawn on a periodic basis (to allow time for the commercial controls above to trigger corrections where the discrepancy is identified) and prioritised by the size of the discrepancies.
- 2) A self-compliance regulating model, where there is responsibility on the parties involved in each movement or change of ownership to reconcile discrepancies between dispatched and received goods should these be identified. This may be implemented either as a mechanism where at the time Organisation A submits a traceability dispatch event, the quantities and package identifiers are sent by the traceability solution to Organisation B, against which they reconcile the receipt. This entails an obligation on both parties to agree and reconcile any discrepancies as they occur (at a transaction level).
- 3) A hybrid approach between 1 and 2, in which parties only report receipt and dispatch events. However, the system actively does a reconciliation between events, and in the event of a discrepancy, notifies both parties, with the expectation that this would trigger a reconciliation exercise between the parties.

Model 1 poses the highest risk on the data integrity of the solution, and potentially a high administrative burden on Member State authorities to follow-up cases that may appear as intentional non-compliance, but in fact are administrative errors. Model 2 migrates a large portion of the burden from the Member States back to the parties concerned – but effectively doubles the messaging between systems and requires all stakeholder systems to be able to receive traceability data events and submit in order to perform a reconciliation process. Model 3 avoids some of the system complexity, at least on the manufacturer and distribution economic operator solutions, though the data management provider would still need to perform a reconciliation process on all traceability event

receipts in order to generate the notifications. A further consideration may be to consider what extent these three models align to the consideration of “Due Diligence” as outlined in Article 7 of the FCTC Protocol.

Given the impacts of these different models on the various stakeholders, as well as the traceability solution itself, a recommended implementation path may be to begin with model 1, knowing that the discrepancies can be monitored over time. In the event false alerts and data discrepancies warrant concern, this could build the business case to extend the traceability solution to model 3 (either for all operators, or targeted at those areas of identified risk), and if further control is required, move towards model 2, should the operating burden on distribution economic operators be warranted.

The purpose of this report is not to prepare a solution design or prescribe functional requirements, but rather to highlight potential implications of a traceability solution. This is therefore highlighted as such an area that may warrant further debate and discussion. This may be especially important as some of these considerations may require additional responsibilities to be assigned to manufacturers and economic operators, and therefore will need to be considered during development of any implementing legislation.

How could a self-regulating compliance model work?

In a self-regulating compliance supply chain, normal business practices and procedures of the supply chain should be leveraged to provide opportunities for compliance management and exception reporting. This can be achieved by giving supply chain entities access to the information they require in order to manage and regulate themselves, and providing an opportunity for proactive detection and treatment of any anomalies.

In addition, a mandate of cumulative compliance should be adopted by all entities involved to ensure that there are no weak links across the supply chain. This would require each entity within the supply chain to confirm and corroborate the data as captured by the entity before them in the chain.

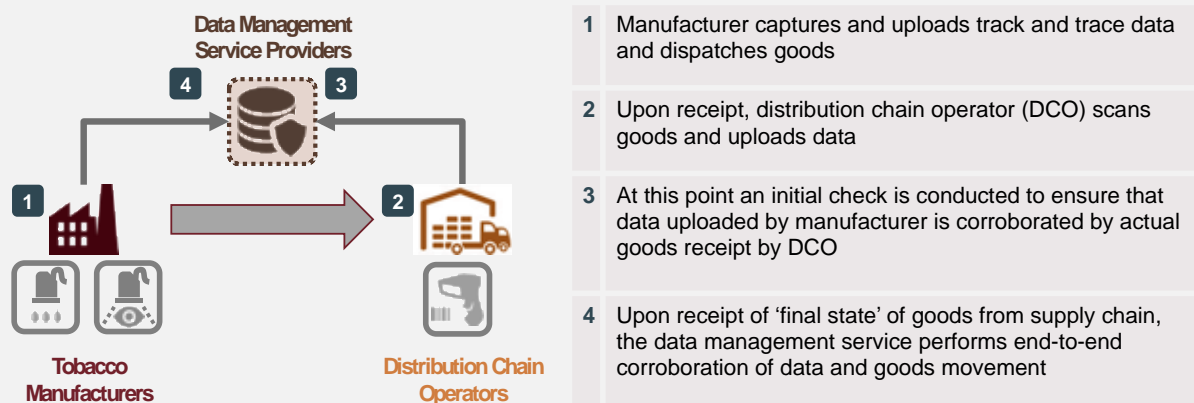


Figure 46: Self Regulating Supply Chain Cumulative Compliance Model

The model above illustrates a potential way this could be achieved. The data management provider compares dispatches and receipt events between operators at each supply chain event. In the case of any discrepancies, potentially a ‘discrepancy event’ could be recorded and relevant notification would be sent to the two parties entities involved. This could be used as a basis to prompt checking and corrective action. Such automated active supervision of the supply chain and the traceability solution with reconciliation activities by the operators themselves could reduce the need for periodic post audit activities by EU and Member State authorities.

8.6.7 GRANULARITY OF RECORDED TRACEABILITY EVENTS

During a number of distribution chain operations, the exit of unit packets from the possession of one party happens simultaneously with the entry of possession to the next

party. As an example, consider tobacco products on wrapped pallets that are stored in a manufacturer’s warehouse awaiting transport by a logistics provider to the customer. The order is staged in the dispatch area, and once the truck arrives, the pallets are immediately loaded onto the transport. During this loading operation, the barcode of each pallet is read to record its unique identifier and to associate it with the dispatch event that will be reported by the manufacturer.

Following this logistics event there are three proposed traceability granularity levels:

- A. **Dispatch Events from Facilities:** A traceability record is submitted by the distribution chain operators and manufacturers at the time of dispatch, indicating the intended destination and the transporter. In level A, there would hypothetically be no further obligation on the transporter to report the movement, or on the receiving party to report the receipt of the tobacco products;
- B. **Receipt & Dispatch Events between Facilities:** A traceability record is submitted by the distribution chain operators and manufacturers at the time of receipt and dispatch of tobacco products. Dispatch events would include indicating the intended destination and the transporter (logistics provider); or
- C. **Receipt, Dispatch, Movement and Transport Events:** At this level, in addition to the events described in level B above, the logistics provider scans the items received for transport. This would have to happen almost simultaneously, as the manufacturer scans the items to record their dispatch.

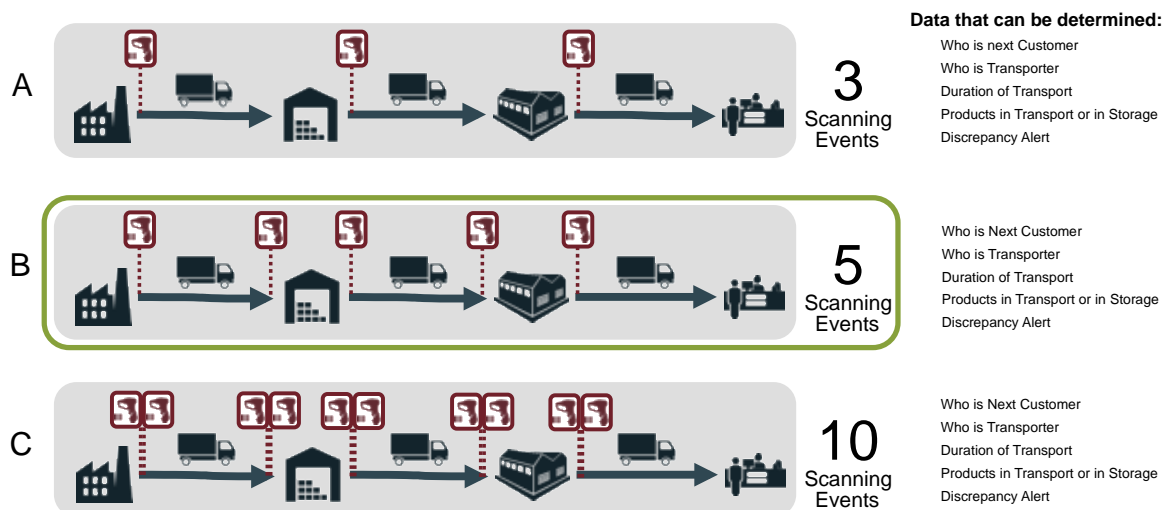


Figure 47: Implied Traceability Model

Level B provides a balance of process efficiency and proportionality of the supply chain impact and information controls. As compared to Level C, Level B provides the same key data elements for monitoring the distribution chain, but considerably fewer scanning events. Level A has the least number of scanning events, but also does not provide the EU and Member State authorities with a clear indication of when tobacco products are in transit or have reached their destination and are in storage. Level C results in almost double the number of scanning events, but arguably these are largely duplicated efforts with limited additional traceability information collected or benefit provided.

INDICATION OF TOBACCO PRODUCTS IN STORAGE OR IN TRANSIT

A key principle in all 3 cases above and across all 4 option, is that the traceability solution should provide EU and Member State authorities with clear confirmation of whether particular tobacco products are in transit or in storage. This should be unambiguous when querying the status of a particular tobacco unit, and can assist

Customs, Excise or Law Enforcement officials in the field to verify the status of a tobacco shipment identified in the field.

To achieve this, timing requirements should be specified in terms of traceability data that is received from the responsible manufacturer or distribution operators. The unique identifiers of tobacco units, aggregation data and dispatch event (including the details of the transport and receiving operator in the distribution chain) should be submitted and uploaded to the data management provider **prior to the physical movement of the consignment** from the manufacturer's or distribution operator's dispatch facilities. This ensures that the traceability solution is able to clearly indicate which tobacco products shipments are currently being transported.

8.6.8 POTENTIAL LINKAGES WITH EU CUSTOMS AND EU EXCISE SYSTEMS

Recognising that a primary objective of the TPD is to combat non-compliant products being distributed on the internal market, this report examines further the potential linkages (and potential benefits) between a tobacco traceability solution and the areas of taxation and /or Customs that may share a related objective in combatting illicit trade. There are a number of government agencies that are interested in, may benefit from and may be affected by a traceability solution for tobacco control in the EU. Excise functions and Customs functions will both need to be considered in terms of operational impact, since they both deal with the same supply chain entities for various regulatory reasons.

The intention of this section is not to develop solution designs but rather to highlight key considerations for future discussions between the EU and Member States authorities.

Considering the mandates of Customs and Excise agencies within EU, there are similarities with regards to the control of tobacco products. The mandate for most Customs organisations is two-fold:

1. Secure the supply chain (importation, exportation and transit) and protect society from illicit and harmful goods; and
2. Collect all revenues due and prevent revenue loss.

Similarly, Excise organisations are driven by the objective to:

3. Control the manufacture, distribution and sale of excisable goods by collecting tax revenue and preventing illicit trade.

While the base legal framework and operational activities employed by these two respective agencies in fulfilling their mandates are distinct, there is potentially some overlap in the degree to which a traceability solution can provide a method to identify tobacco goods, provide information related to their movement and provide a mechanism to authenticate that they are legitimate. Further, traceability data of legitimate tobacco movements may provide an additional data source to aid risk management efforts of both these agencies assisting in the ability to identify, categorise, prioritise and mitigate risks.

Considering the mandates of these organisations and their congruency with the drivers for a traceability solution, possible linkages between these solutions bears further investigation and consideration.

8.6.8.1 CUSTOMS

Core to the Customs process is a goods "declaration" that indicates an intention to import, export or transit goods. This formal process allows a party to indicate which customs procedure the goods should be placed (as provided for by the Community

Customs Code) and this declaration is submitted by the owner (person or company) of the goods or a person acting on their behalf (a representative). In addition, pre-arrival and pre-departure declarations are provided to support pre-arrival and pre-departure risk analysis (Entry Summary Declarations, Exit Summary Declarations, or import / export / transit declarations where the required pre-arrival/pre-departure data is included at the relevant moment in time).

To fulfil their mandate, Customs organisations use risk management (and in particular electronic risk analysis) to differentiate between the levels of risk associated with goods and to determine whether or not and if so where the goods will be subject to specific customs controls mainly operational controls (validation, documentary, non-intrusive inspection, physical controls) and post-clearance controls (such as audit). Customs risk management involves the systematic identification of risk and implementation of all measures necessary for limiting exposure to risk, and includes activities such as:

- collecting data and information;
- analysing and assessing risk;
- prescribing and taking action; and
- regular monitoring and review of the process and its outcomes.

In this context, it is anticipated that tobacco traceability could:

- Assist risk analysis and operational control functions in relation to legitimate tobacco products destined for the EU and also by helping distinguish tobacco products compliant with Article 15;
- Provide data to aid post-clearance controls (e.g. audit - in so far as they relate to tobacco products); and
- Provide a rich data source to support risk management.

The above-mentioned workflows and controls are carried out at Member State level, and within the framework of the customs Common Risk Management Framework with the support of the Commission. The TPD, under Article 15 states that traceability requirements apply to tobacco products manufactured outside of the EU, which are "destined for, or placed on, the EU market".

IMPORTS (MOVEMENTS FROM OUTSIDE OF THE EU TO A MEMBER STATE WITHIN THE EU)

Based on the TPD requirements and the proposed solutions in the sections above, any products manufactured outside of the EU and destined for consumption within the EU will have to conform to the agreed traceability and security feature requirements. Furthermore, this would necessitate that the production and movement event data for those products intended for the EU market, have been uploaded and stored by the traceability data management solution.

With regards to the importation of tobacco products into the EU, the first point of control or intervention will be at the border where the products enter the EU, and will most likely be carried out by the Customs administration of the relevant Member State. Even prior to the departure for or arrival of goods (depending on the mode and duration of transport) at the EU frontier, a declaration will be submitted, stating the intention to move tobacco products from outside the EU into a country within the EU.

- Traceability information provided during the manufacture of goods destined for the EU market, and linked to the associated import or pre-arrival / pre-departure declaration could aid Customs officers based at the EU border in verifying – from pallet down to tobacco unit level in need - the legitimacy of such goods linked to the import movement.

- This would apply to the Customs authority in the Member State into which the goods are being imported, as well as the Customs authority of Member States through which tobacco products are being transited for entry into another Member State.
- This could aid with risk analysis for control purposes and aid with documentary and physical goods reconciliation.

EXPORTS: (MOVEMENT OF PRODUCTS FROM AN EU MEMBER STATE TO A COUNTRY OUTSIDE THE EU)

Regardless of the solution adopted from the options mentioned above, it is understood that any goods produced within the EU must conform to the requirements of the traceability solution as defined within the TPD. This means that it should bear the traceability as stipulated by the chosen solution option, and that all events regarding such production and movement should be recorded and submitted to the data management provider.

In **Error! Reference source not found.**, an example is illustrated where tobacco products are produced in a factory in Italy, but intended for Export (outside the EU) to a North African country. At the time of manufacture, it is envisaged that the unique identifiers of tobacco units, packaging (aggregation) would be recorded, and by the time of shipment from the manufacturer this data would be submitted to the data management provider. This submission would include information related to the intended market for those particular products, and details of the purchaser and goods transport.



Figure 48: Export movement out of the EU

Creating a link with the tobacco traceability event and the Customs export process and customs risk management systems will support assessment of risks at the time of the declaration and also verification that goods produced with the intent of Export, actually do leave the EU and do not end up in local consumption. In particular, this link between the traceability data and the Export declaration could potentially be used to use the Customs transaction and exit confirmation as a mechanism to reconcile these volumes with the traceability solution.

The corollary of this is the information that the traceability solution could provide to Customs organisations of respective Member States. In the example above, Italy Customs would be interested in confirming the volume and types of products that were declared for Export, and the traceability system could provide information related to physical products that were reported as moving across the border, including unique identifiers of the tobacco units and associated packaging (aggregation hierarchy) that may also support any control activities that may be performed.

Downstream this has an important advantage that potential diversion (or ghost export) activities (not already signalled from risk analysis) have the potential of being detected. If routine or ad hoc inspections are conducted in Member States within the EU and identify tobacco products which traceability information reveals that they should have been exported, then this could serve as a trigger for enforcement actions that Customs could take against the party that was meant to have exported such products and support customs risk management in general.

Based on the above, it is not envisaged that direct integration between the traceability solution and Customs solutions is necessary to apply such controls, assuming the solution allows systematic real-time export of data to the Customs solutions, both at EU and MS level so that national customs and the Commission would be able to use it for real-time customs risk management purposes in the relevant systems. Customs organisations could also benefit from utilising traceability information as either a third party confirmation of Import of goods entering into the EU or as validation of volumes produced for Export of goods out of the EU. However this question of whether direct integration is needed (and in that context, details such as the feasibility of a linking reference) should be considered further by Member States and the Commission during the next project stages.

8.6.8.2 EXCISE

Excise duties are indirect taxes on the consumption or the use of certain products. In contrast to Value Added Tax (VAT), they can consist of both ad valorem and specific taxes (generally more prevalent), i.e. expressed as a monetary amount per **quantity** of the product.

All EU Member States apply excise duties to manufactured tobacco products. These revenues, together with excise revenue from alcoholic beverages and energy products, accrues entirely to the Member States.¹¹² According to the Horizontal Excise Directive 2011/64/EU¹¹³, Member States have to apply a specific excise duty per unit of the product and a proportional excise duty calculated on the basis of the weighted average retail selling price. Furthermore, Member States may choose between either an ad valorem duty, or a specific duty or a mixture of both on manufactured tobacco other than cigarettes.

Based on the Horizontal Excise directive and the need for a control mechanism for Excise movements under duty suspension, a union-based control system was envisioned to augment Member-based control of Excise goods and products. This heralded the introduction of the **Excise Movement and Control System (EMCS)**.¹¹⁴ [A brief overview of the EMCS system is included as Annexure 8 below].

The EMCS policy and regulations are applicable at the EU level and only cover excise duty suspension movements between consignees and consignors across Member States. The administration and control is applied at a Member State level, by the Member State agency, usually the Excise agency.

This declaration of movement is done at a consignment or consolidated movement level. It should be noted that in comparison, it is envisaged that the traceability solution would track movements at a more granular level of detail by specifying the identification of goods down to the unit / item level (through the process of aggregation recording). The efficacy of the EMCS solution is dependent upon the declarations made by the consignee and consignors, and thus the control is primarily an acquittal process allowing reconciliation between dispatch and arrival of the goods.

There is therefore a potential benefit to establish a link between the EMCS and the tobacco traceability solution. The objective of such a link would be to cross-leverage regulation; administration, resources and control opportunities presented by both applications and provide a cargo-based control of these movements. Excise agencies would benefit from track and trace information, as it would bolster their cargo control

¹¹² http://ec.europa.eu/taxation_customs/taxation/excise_duties/gen_overview/index_en.htm

¹¹³ Council Directive 2011/64/EU

¹¹⁴

http://ec.europa.eu/taxation_customs/taxation/excise_duties/circulation_control/emcs_practice/index_en.htm

and goods accounting capabilities. The tobacco traceability solution could leverage the Excise resources and data for audit and volume validation purposes.

Ideally, the link should provide the basis for automated reconciliations and alerts, a potential consideration during the upcoming traceability solution design activities.

POTENTIAL LINKAGES BETWEEN THE TRACEABILITY SOLUTION AND EMCS

The possibility of EMCS integration needs to be looked into more deeply as there are a number of different ways that integration could be achieved, with different possible synergies. Some considerations may include an ambit of options that present a progressively more controlled procedure for Excise duty suspension through linkages, data sharing and process sharing between the traceability solution and EMCS.

- **Option A: No system based linkage – cross reference during risk-based interventions:** Track and trace information is available via access to the database on a request basis. This access is used by relevant Member State Excise officers and will be used for verification of specific transactions selected using risk analysis. For these cases the track and trace movements will be compared against the EMCS movements to identify anomalous patterns, non-compliant traders and other risk triggers.
- **Option B: Traceability provides electronic supporting document:** When submitting an Excise declaration (E-AD), the declarant will include any track and trace data related to that movement as an electronic supporting document. This can be used by the Excise organisation in their risk assessment during documentary control and for reference during any further audit or physical interventions.
- **Option C: Data linkage:** This option entails creating a linkage between the traceability event data and EMCS. This could potentially occur as either a change to the Excise declaration data model (E-AD) to allow the inclusion of dematerialised traceability data, or inclusion of a reference to the EMCS movement number as part of the Traceability event data submission. The distinction between this option and the electronic supporting document above, is that since the information is dematerialised it can be directly validated by either the traceability solution or EMCS and be utilised by the risk management systems for data verification, requiring only identified exceptions to be processed by an officer.

Due to EMCS being a community system, a potential consideration may be a progressive integration model, whereby **Option A** is introduced to establish the connection between the traceability solution and EMCS, followed by the introduction of **Option B** to enable the attachment of traceability data by declarants, which will provide more input for transaction based risk analysis and will remove some of the post clearance audit work required to verify data. Finally, introducing **Option C**, which would enable real-time automated processing and risk analysis of Excise and Traceability data. A further advantage of this option is it allows reconciliation to take place at the close of each eAD movement transaction, instead of periodic reconciliation aggregating data of several months which is often associated with effort expended on investigating discrepancies and timing differences.

The advantage of a staggered approach is that initial benefits can be realised by integrating at the Option A level and then based on Member State findings, the business case can be considered to progress to Options B and then C.

The proposed linkage models provide an advantage by using the traceability solution to monitor the movement of actual goods (to the pack level if required), which augments the current tracking of information by the EMCS system. It poses an opportunity for cargo control of Excise movements under duty suspension, potentially better risk

management and offers the ability for the EU Commission and other interested parties to consolidate resources by sharing solution platforms. The added advantage of this integration is that it adds no additional impact to the trade (over and above meeting their obligations of the tobacco traceability solution). Based on these potential advantages, it is recommended that the upcoming activities include the initiation of a project to scope and develop business requirements to validate the possibility of linking the traceability solution with EMCS.

POTENTIAL BENEFITS OF TOBACCO TRACEABILITY DATA TO SUPPORT EXCISE OPERATIONS

While the primary purpose of the TPD in terms of tobacco traceability is reduction of non-compliant products entering the internal market – tobacco traceability data could also aid tax revenue management efforts in the tobacco sector. Some potential benefits for consideration by Member State Excise authorities may include:

- Using the tobacco traceability data as supporting data to reconcile monthly Excise revenue declarations. This may also provide an element of additional assurance to Member State authorities where the tobacco traceability data is recorded by a party independent of the tobacco manufacturer.
- Provides production data for forecasts (including seasonality and trends) of Excise Duty, VAT, and potentially Corporate tax collections in relation to the tobacco sector
- Record data on market surveillance activities to identify illicit products on the internal market, identify non-compliance “hotspots”. May also be used to provide Excise administration management teams with oversight of market surveillance teams location and adherence to sampling methods (see 8.6.11 below for potential market surveillance activities that may be recorded).

8.6.9 RELATED COMMERCIAL DOCUMENTS SUPPORTING TRACEABILITY EVENTS

Article 15 §2 TPD indicates that the unique identifier should allow “the invoice, order number and payment records of all purchasers from the manufacturing to the first retail outlet” to be determined.

Interpretation of this article implies that this information be ‘accessible’ via the unique identifier, whether stored by the respective supply chain entity or stored as part of the track and trace information in the data stores.

There are three methods for the required information to be recorded and stored:

- **Reference to Supporting Documents:** Required data will be stored by the respective supply chain entities and will be made available upon request utilising the unique identifier as the key for the record. The advantage of this method is that there is no additional need for data storage of all the record information (which is significant), as it will be stored by the owner of the data. Related to this is the security and ownership of such data is not brought into question, as only requested data will be accessed via the Commission and member states. A potential drawback is that in-depth analysis and data mining across the EU and member states cannot be done as all the data will not be available for scrutiny.
- **Stored as a Supporting Document:** This method implies converting the commercial documents and information into a format that can be transmitted, stored and analysed at a high-level. Examples of this would be PDF, JPG, etc. The advantage of this method is that original copies of commercial documents will be readily available and accessible by the commission and member stats for analysis,

risk assessment and enforcement initiatives. The drawback to this option is the considerable storage requirements for all of these commercial documents in image format¹¹⁵, and related to that would be the security and ownership of such information.

- Dematerialised Storage (Supporting Document Data):** Dematerialisation of commercial documents means the digitisation of all the data on such documents. Simply put, converting the data on the commercial document into a structured data field. This would make all the fields within the document available for data mining, analysis, projections, simulation and many other advantages to structured data. This is no insignificant task as it implies the standardisation and formalisation of these documents across the EU but potentially could provide such a wealth of data for the Commission and Member States that it should be considered as a long-term goal. The World Customs Organisation (WCO) has been promoting the dematerialisation of documents for a number of years and experience from such initiatives could be leveraged.

A summary of these three methods is shown below. Note that with each progressive model, the usability of the data to support automated analysis and risk assessment increases, simultaneously with the implementation burden on stakeholders.

	By link to document reference #	Submitted as supporting document	Submitted as electronic document
ILLUSTRATION	<pre><OrderNumber> 002980040 <InvoiceNumber> A794890001</pre>		<pre> i>IC*040713*1001*040625*P89320~ DocumentHeader: #####EF*AN*547794~ #####PER*BD*JOHN BONES*TE*5552225555~ #####N1*BT*ACMEDISTRIBUTING/COMPANY~ #####N3*601FIRSTSTREET~ #####N4*CROSSROADS*MI*48106~ #####OB*PB~ DocumentLineItems: CTP*MS*PCP*12.5~ PID**08***ITEMDESCRIPTION/1018~ SAC*A*8280***20.00**2.00***02~ </pre>
Documents available on Request			
Immediately available to EU & MS Officials	-		
Prevent document changes after submission	-		
Format suitable for automated analysis (e.g. risk engine processing)	-	-	
Implementation Complexity for Stakeholders			
Extended support for automation of Law Enforcement & other Traceability objectives			

Low
 Medium
 High

Therefore, perhaps the most appropriate approach for the tobacco traceability solution would be a phased approach beginning with method 1 and progressing towards method 3, if the need for such structured data proves a requirement in the future.

8.6.10 EXTENSIONS REQUIRED TO CURRENT STANDARDS FOR TRACEABILITY INFORMATION EXCHANGE

The report identifies that EPCIS technical standards, as promoted by GS1, provides a useful standard for the capture, exchange and querying of traceability event data. The current data and business events as defined relate primarily to the identification of unique items and their movement through a supply chain / logistics environment. The

¹¹⁵ The estimated data storage size for Method 2 and Method 3 have not been modelled as part of this report and this modelling exercise should be included as part of the requirements analysis in the next project phases.

standard supports the use of extensions for additional data elements and business events to be recorded using the same messages.

Given the traceability data requirements outlined in the TPD, in particular Article 15(2), (5) and (7), the EPCIS messages will need to be extended for dispatch notifications (whether from Manufacturer or from Distribution Chain Operator facilities) to include identification and details of the transporter, and details related to the next customer.

Further, taking into account the further traceability considerations described in this report, examples of further extensions that may warrant further consideration include:

- Additional business event information to record the change in tax paid status of tobacco products; and
- Business events related to reconciliation and discrepancy notification events (e.g. identification of short-shipped tobacco items by the recipient).

It is therefore proposed that during subsequent project phases, technical representatives of European Commission directorates and Member State parties consider participation in the technical forums as a mechanism to facilitate implementation of these extensions in a manner acceptable to both industry and government stakeholders.

8.6.11 FIELD INSPECTION SUPPORT AND SECURITY CONSIDERATIONS

For all four traceability options discussed above, it will be required that EU and Member State officials be provided a mechanism to access the tobacco traceability data for market surveillance and field support purposes.

It is proposed that a range of field inspection support solutions is offered to accommodate the needs from different stakeholder user groups. As a suggestion only, the table below provides an indication of the stakeholders that may utilise devices and / or services, taking account the different levels of required sophistication. These options propose using smartphone devices

	Simple Traceability Application	Field Support Application
Intended Users	Police services, Customs border control	Enforcement Officials working specifically in the domain of tobacco control (OLAF Tobacco control, Excise Officers, market surveillance)
User Frequency	Occasional	Related to primary job function
Application Type	Web Portal (accessible using any mobile / desktop web browser)	Mobile Application developed specific devices (requires agreement with EU and Member State Authorities)
Supported Devices	Desktop, Laptop, Mobile Phone with data connectivity and Mobile Web Browser	Approved Smartphone and Mobile Devices
Connectivity Support	Online only	Online and offline

	Simple Traceability Application	Field Support Application
Functionality	<p>Manual capture of Human Readable Code Unique Identifier Code or Scan of Machine Readable Code (supported in some cases)</p> <p>Online:</p> <p>Simple Traceability Queries (Item information, Current Status, Previous Event History)</p> <p>Validate Aggregation Hierarchy (other goods in shipment and integrity of packaging levels)</p> <p>Report Suspicious Activity</p>	<p>Reading of Machine Readable Code (Primary), with capture of Human Readable Code in Exceptions only</p> <p>Offline:</p> <p>Decode information that forms part of unique identifier (manufacture date and time, manufacture location, intended marked, etc.).</p> <p>Bulk capture for subsequent online validation (e.g. Warehouse bulk check where connectivity may be intermittent)</p> <p>Online:</p> <p>Simple Traceability Queries (Item, Current Status, Previous Event History)</p> <p>Validate Aggregation Hierarchy (other goods in shipment and integrity of packaging levels)</p> <p>View related information (other goods in consignment, Consignee / Consignor / Transporter information)</p> <p>Inspection case workflow (capture of inspection results and findings, evidence capture using camera,</p>
Audit Trail	User, Access history, Location (IP Address)	User, Access history, Location (GPS & IP Address)

Table 37 - Requirements for Field Support Application that may benefit EU and Member State Authorities

Several solution providers surveyed indicated the availability of a dedicated mobile inspection device. In considering the use of such devices, the needs of the intended users should be taken into account. A dedicated device may be suitable for full time market surveillance and inspection teams, where the inadequacies of a smartphone / consumer grade device may be problematic. However, for infrequent users (such as border management officials or police services), the flexibility and convenience of a smartphone based application may be advantageous, even if the functionality may have some limitations.

Some of the field inspection equipment provided offered by some solution providers offers a combined feature where the traceability information is presented to the user whilst simultaneously the covert security elements of the security feature are authenticated.

There are a number of security considerations related to the inspection application, both in terms of allowed access, and information recorded for audit purposes. Across all four options it is strongly recommend that:

- The confidential nature of tobacco traceability information is preserved, with industry practices for access control to the traceability data. ISO16678: 2014(E), "Guidelines for interoperable objective identification and related authentication systems to deter counterfeiting and illicit trade" guides recommend that there be a means to verify an inspector's identity and organization affiliation before access

to confidential information is granted, with access control utilizing a digital certificate a consideration for highly confidential data.

- A full audit log of inspector activity is maintained. This should include access logs detailing when unique identifier codes (UID) were checked, optionally by which inspector, and optionally from what specific location.

8.6.12 SOLUTION SUPERVISION AND CONTROLS

A critical aspect for consideration when proposing any new solution is the supervision and control requirements for that solution. If these controls are not adequately designed and implemented it would undermine the overall efficacy of the solution.

Control, as discussed in this section, refers to the measure of the implementation or operationalization of the solution against the pre-defined design, plan and objectives. Considering the traceability solution is a 'checking mechanism' on the tobacco supply chain, the control elaborated on below alludes to a 'check' on the checking system. The aim of this check would be to ensure that the solution, is implemented, supported and maintained to the standards required.

The means for achieving this supervision and control would be the development of a framework that outlines the guiding principles and defines the requirements for such control. In the case of the traceability solutions being proposed in the sections above, this framework would be generic across all solution options but will have specific nuances based on the different solution models for Option 1 and 2. Options 3 and 4 would be derivatives of Options 1 and 2 as a result of their similarities.

Control Framework: Guiding Principles

1	Where available and reliable, third party data for validation and verification must be utilised in order to corroborate the data and processes of the traceability solution.
2	All dimensions of control should be systematically and periodically checked to ensure continued compliance to standards and requirements.
3	Where possible, self-regulating and automated controls should be employed.
4	Supervision and control should be applied at various levels of over-sight to ensure end-to-end integrity of the solution. This can be done at the industry, Member State and EU Commission level.
5	Standards, policies and procedures should be periodically reviewed and refreshed to ensure the solution remains effective in achieving defined objectives.


These guiding principles must be considered when designing a control framework for the traceability solution. Control of the traceability solution will be required across many dimensions and for each stakeholder within the supply chain.



Dimensions of Control

Operational	Control of the operational environment where the solution is implemented. From the point of manufacture to consumption to ensure that adequate control of resources, sites and distribution channels is in place in terms of security and processing to meet the solution requirements.
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Dimensions of Control	
Data	Control of the data and information accumulated and passed between entities within the scope of the solution. Does the data meet the standards as prescribed? Is it collected in a timely manner and correctly? Is it accurate and reliable and can the source be trusted? Linked to this dimension is Data Storage : The wealth of this solution is the accumulation of data. The storage, reliability, redundancy and availability of this data will have to be continuously checked and maintained to ensure effectiveness.
Hardware	Hardware in the form of the marking and scanning tools is critical to the efficacy of the solution. Control of this hardware would entail ensuring readability of the unique identifiers, correct information recorded and submitted, system reliability and effectiveness.
Software	Like the hardware being used, the software utilised to drive the solution will have to be interrogated and maintained to ensure it remains fit for purpose and of the highest quality within the prescribed parameters.

The table below expands on control measures per stakeholder required to address the dimensions mentioned above. A number of these measures could very likely already be in place for many of these stakeholders but they bear mentioning in order to establish an agreed control baseline for all stakeholders within the supply chain.

Stakeholder	Control Measures
 Tobacco Manufacturers	<p>OPERATIONAL</p> <ul style="list-style-type: none"> ▪ Tobacco Manufactures (TMs) implement certified security measures to ensure adequate security of the manufacturing sites and resources employed at these sites to prevent leakage of goods and information. ▪ TMs implement stock control system and measures to adequately monitor and control movement of stock into and out of the facilities. ▪ TMs implement a production line monitoring mechanism. This could be managed and provided by the manufacturer or an independent third party with the primary objective of monitoring total production of every line independent of traceability reporting. These recorded values should be regularly reconciled against manufacturers own records to ensure the traceability solution is operating correctly. ▪ TMs use an independent third party to conduct scheduled and un-scheduled periodic audits of the manufacturing sites which would include a review of the following: <ul style="list-style-type: none"> ○ Administrative: comparing reported production figures against financial and economic data in order to confirm that what has been reported is actually what was produced. ○ Site: ensuring the manufacturing site still meets requirements stipulated for a secure facility. ○ Production line: ensuring that the production lines in use match the ones being reported. Review utilisation and account for downtime. Check the production line

Stakeholder	Control Measures
 <p>Tobacco Manufacturers - continued</p>	<p>monitoring mechanism.</p> <ul style="list-style-type: none"> ○ Inputs/Outputs: comparing and accounting for the raw material inputs (tobacco, filters, package materials etc.) against finished product outputs (packages). <p>HARDWARE</p> <ul style="list-style-type: none"> ▪ TMs implement hardware that enables traceability solution components to be periodically tested and checked to verify correct operation. ▪ TMs utilize quality control mechanisms to ensure on-going verification of the traceability solution (e.g. quality and readability of unique identifiers) to record success and fail events. <p>SOFTWARE</p> <ul style="list-style-type: none"> ▪ TMs utilize software that enables the traceability solution, whether provided by industry or third party, to conform to standards and specifications as defined by the EU Commission. ▪ TMs carry out periodic checks of the software results to ensure correct operation. <p>DATA</p> <ul style="list-style-type: none"> ▪ TMs ensure that own data records are secured and replicated to ensure redundancy and availability. ▪ TMs ensure that local data storage is periodically audited against the traceability solution data store to ensure correlation of uploaded and stored data.
 <p>Distribution Chain Operators</p>	<p>OPERATIONAL</p> <ul style="list-style-type: none"> ▪ DCOs implement certified security measures to ensure adequate security of the distribution sites and resources employed at these sites to prevent leakage of goods and information ▪ DCOs implement stock control system and measures to adequately monitor and control movement of stock into and out of the facilities <p>HARDWARE</p> <ul style="list-style-type: none"> ▪ DCOs periodically test and check scanning devices and other track and trace tools to ensure they function correctly. <p>SOFTWARE</p> <ul style="list-style-type: none"> ▪ DCOs utilize software that enables the traceability solution, whether provided by industry or third party, conforms to standards and specifications as defined by the EU Commission. ▪ DCOs carry out period checks of the software to ensure effectiveness.

Stakeholder	Control Measures
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Data
Management
Provider

OPERATIONAL

- Data Management Providers (DMP) implement certified security measures to ensure adequate security of the data storage sites and resources employed at these sites to prevent leakage of information.¹¹⁶
- DMP replicate data to off-site disaster recovery site. Continuous update and refresh of DR data to ensure reliability and availability.

HARDWARE

- DMP utilize hardware, whether provided by industry or third party that conforms to standards and specifications as defined by the EU Commission.
- DMP periodically test and checks the disk storage and other tools implemented to enable the traceability solution to ensure their efficiency and effectiveness.

SOFTWARE

- DMP utilize software to validate that the traceability solution, whether provided by industry or third party, conforms to standards and specifications as defined by the EU Commission.
- DMP conducts period checks of the software to ensure effectiveness.

DATA

- DMP carries out continuous monitoring of data uploaded from manufacturers and compares it against goods receipted by distribution chain operators and other recipients. This is to confirm correlation of all data uploaded and acquit the data against the goods
- DMP generates periodic reports for all stakeholders informing them of their track and trace activity. Furthermore, an exception and discrepancy report should be prepared for Member State and EU authorities to take action as required.
- DMP periodically carries out database redundancy checks
- DMP conducts random checks of data availability and accuracy ensures data reliability.

¹¹⁶ Recommendation that security standards should be built around COBIT (Control Objective DS11.6 – Data security as a standard, which defines storage, transmission, receipt and secure processing of data). Also covered under ISO 27001:2013 – Information Security Management and ISO 27002:2013 – Information technology – Security techniques – Code of practice for information security controls

Stakeholder	Control Measures
 <p data-bbox="183 387 395 450">Member State Authorities</p>	<p data-bbox="406 309 630 338">OPERATIONAL</p> <ul data-bbox="454 360 1418 869" style="list-style-type: none"> <li data-bbox="454 360 1418 555">▪ Member State Authorities (MSs) conduct scheduled and un-scheduled periodic audits of supply chain entities to ensure compliance with tobacco control policies and procedures. These audits would most likely be carried out by Member State Customs/Excise agencies and combined with their routine audits, which typically look at volume and revenue checks. <li data-bbox="454 566 1418 689">▪ The MSs would expand the scope of their audits to include checks on track and trace related aspects. Reports from these audits should be fed back into the traceability solution and stored as such. <li data-bbox="454 701 1418 869">▪ MSs would have to consider the impact of such increases in audit scope against their current resource capacity and utilisation in order to determine if additional capacity will be needed to fulfil the requirements of the number of supply chain entities in the Member State. <p data-bbox="406 902 587 931">HARDWARE</p> <ul data-bbox="454 954 1418 1014" style="list-style-type: none"> <li data-bbox="454 954 1418 1014">▪ MSs must periodically test and check scanning devices and other track and trace tools to ensure their efficiency and effectiveness. <p data-bbox="406 1048 576 1077">SOFTWARE</p> <ul data-bbox="454 1099 1418 1272" style="list-style-type: none"> <li data-bbox="454 1099 1418 1193">▪ MSs must utilize software to enable the traceability solution, whether provided by industry or third party that conforms to standards and specifications as defined by the EU Commission. <li data-bbox="454 1205 1418 1272">▪ MSs should conduct periodic checks of the software to ensure effectiveness. <p data-bbox="406 1305 491 1335">DATA</p> <ul data-bbox="454 1357 1418 1451" style="list-style-type: none"> <li data-bbox="454 1357 1418 1451">▪ MSs should perform routine and random data checks and comparisons on stored data to confirm reliability and efficacy of end-to-end traceability solution.
 <p data-bbox="183 1597 395 1637">EU Authorities</p>	<p data-bbox="406 1518 630 1547">OPERATIONAL</p> <ul data-bbox="454 1570 1418 1771" style="list-style-type: none"> <li data-bbox="454 1570 1418 1664">▪ EU Authorities (EU) periodically reviews standards, policies and procedures to ensure traceability solution remains aligned with defined objectives. <li data-bbox="454 1675 1418 1771">▪ EU commission coordinates efforts at the EU level and provides support to Member States to ensure supervision and control of the traceability solution. <p data-bbox="406 1805 587 1834">HARDWARE</p> <ul data-bbox="454 1856 1418 1995" style="list-style-type: none"> <li data-bbox="454 1856 1418 1917">▪ EU periodically tests and checks scanning devices and other track and trace tools to ensure efficiency and effectiveness. <li data-bbox="454 1928 1418 1995">▪ EU utilizes software to enable the traceability solution, whether provided by industry or third party that conforms to standards



Member State Authorities

OPERATIONAL

- Member State Authorities (MSs) conduct scheduled and un-scheduled periodic audits of supply chain entities to ensure compliance with tobacco control policies and procedures. These audits would most likely be carried out by Member State Customs/Excise agencies and combined with their routine audits, which typically look at volume and revenue checks.
- The MSs would expand the scope of their audits to include checks on track and trace related aspects. Reports from these audits should be fed back into the traceability solution and stored as such.
- MSs would have to consider the impact of such increases in audit scope against their current resource capacity and utilisation in order to determine if additional capacity will be needed to fulfil the requirements of the number of supply chain entities in the Member State.

HARDWARE

- MSs must periodically test and check scanning devices and other track and trace tools to ensure their efficiency and effectiveness.

SOFTWARE

- MSs must utilize software to enable the traceability solution, whether provided by industry or third party that conforms to standards and specifications as defined by the EU Commission.
- MSs should conduct periodic checks of the software to ensure effectiveness.

DATA

- MSs should perform routine and random data checks and comparisons on stored data to confirm reliability and efficacy of end-to-end traceability solution.




EU Authorities

OPERATIONAL

- EU Authorities (EU) periodically reviews standards, policies and procedures to ensure traceability solution remains aligned with defined objectives.
- EU commission coordinates efforts at the EU level and provides support to Member States to ensure supervision and control of the traceability solution.

HARDWARE

- EU periodically tests and checks scanning devices and other track and trace tools to ensure efficiency and effectiveness.
- EU utilizes software to enable the traceability solution, whether provided by industry or third party that conforms to standards

Stakeholder	Control Measures
 EU Authorities - continued	<p>and specifications as defined by the EU Commission.</p> <ul style="list-style-type: none"> ▪ EU periodically checks the software to ensure effectiveness. <p>DATA</p> <ul style="list-style-type: none"> ▪ EU should perform routine and random data checks and comparisons on stored data to confirm reliability and efficacy of end-to-end traceability solution.

Why is Control Needed?

The control mechanisms and measures mentioned above are not insignificant, and will have an impact on stakeholders in addition to the other tobacco traceability solution requirements. However, the reasons for such control have been explained in the introduction to this section and the implications of having no control is not an option for consideration.

Nevertheless, there will be some stakeholders that will question the need for this additional control and, in fact, question the need for a tobacco traceability solution at all. The sentiment expressed by these stakeholders is that there is already adequate control of the regulated supply chain and that the bigger problem posed comes from the completely unregulated and unmonitored factions that operate under the radar and behind the scenes of current supply chain oversight.

Although this is a valid point that the regulated supply chain does currently have self-imposed monitoring and controls built into their systems, processes and distribution channels, these controls are largely non-standardised, internally focused and more concerned on a micro entity level than on the macro supply chain level. The objective of the traceability solution would provide:

- Necessary standardisation of the control and monitoring mechanisms of the supply chain
- End-to-end focus of the supply chain by mandating policies and procedures for all supply chain entities
- Over-arching oversight of the supply chain

The added advantage of the traceability solution is that by identifying, supervising and controlling the vast majority of stakeholders and product therefrom, it will enable EU and

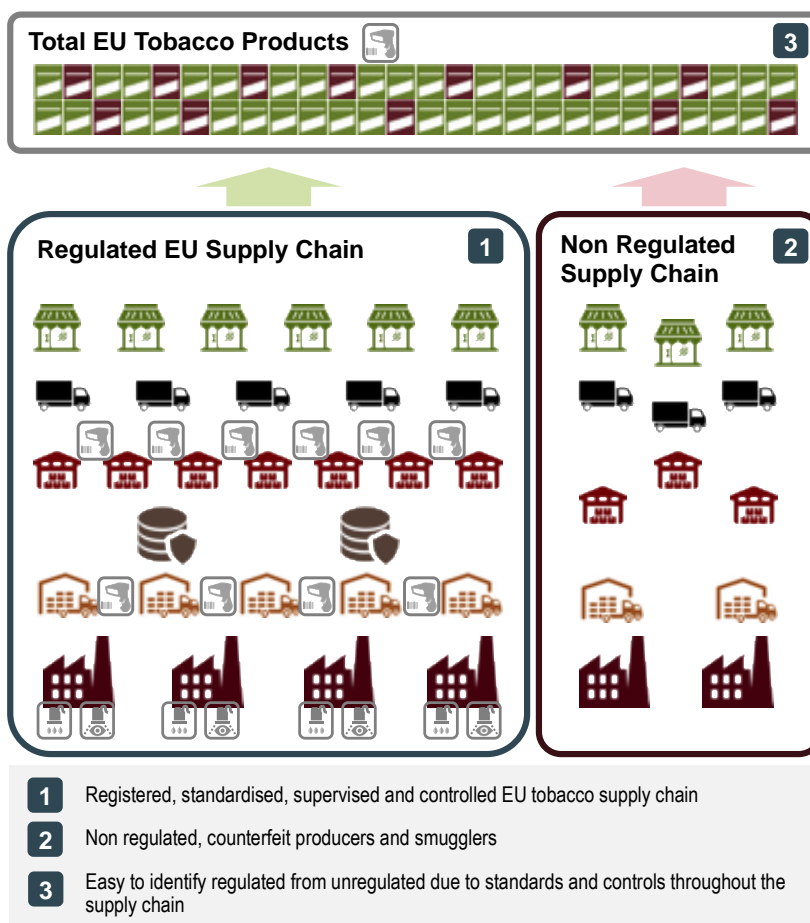


Figure 49 - Regulated vs. Non-regulated Supply Chain Control

Member State enforcement and oversight agencies to focus their risk management and operational resources on the uncontrolled and unregulated stakeholders and products. It is a classic 'segment, control and focus' approach to managing the tobacco supply chain. The figure below illustrates this concept.

If the EU is able to contain the supply of tobacco products by providing standards, policies and procedures, then it can create an 'enclave' of 'trusted' entities. This would imply that there is a sub-set of the total population of manufacturers, distributors, wholesalers and retailers where the products could be trusted as it was traced from point of origin to destination. This would allow and enable the enforcement agencies to focus their attention and resources on identifying and controlling the unregulated and counterfeit goods that are ending up in the EU.

8.6.13 CONSIDERATIONS FOR SMALL PRODUCERS

In review of the above 4 options, the implications on small producers has, as much as possible, been taken into account. While the 4 traceability options indicated by the EU Commission were prepared as discrete considerations for the purposes of determining key implications and providing the basis for a cost benefit analysis, it should be noted that there is some possibility to combine elements of these further.

In particular, Option 4 proposes an approach that may be seen as particularly favourable for small producers, where application of the security feature and unique identifier can be

combined with the possibility of the commissioning event, recorded the application of the security feature with a unique identifier on the tobacco product at the time of manufacture, using a relatively simple handheld device. A consideration for the EU Commission and Member States may therefore be to consider a blended approach, where perhaps Option 1, 2 or 3 are considered for cigarette and roll-your-own tobacco products, while Option 4 might be recommended for the other tobacco products.

9 FOUR OPTIONS FOR SECURITY FEATURES

The following section describes the four security feature packages that were used as a basis for further review as part of the feasibility assessment and cost benefit analysis.

As identified in section 7.2.2 above, there is a diverse range of security features that can be combined to provide a competent security package with overt, "semi-covert", covert and forensic elements. While there are hundreds of combinations and permutations, the project considered four distinct scenarios in proposing the security feature packages options for further evaluation:

1. **A competent security feature package** using similar authentication technologies for consumers and law enforcement officials, as used on a modern tax stamp;
2. A Security Feature package would be required **to supplement a "digital only" solution** (where the unique identifier and associated traceability data are the only means to verify a product). This security feature package would therefore need to provide a basic set of authentication features (overt and forensic) to create stronger measures for the potential detection of fraudulent reproduction of unique identifiers from legitimate onto illicit products;
3. A security package that includes an **emerging security feature** for material fingerprinting; and
4. A combined security feature package that considers **synergy benefits with the traceability solution** (required to complement Traceability Solution Option 4 in 8.5 above).

Recognising that the majority of Member States already have some form of fiscal marking programme in place, the feasibility assessment for these options provide a potential basis for minimum technical standards that may be relevant for those Member States that choose to use the provision in Article 16 §1, and allow these existing markings to be used for the security feature. Those Member States that do not operate a tax stamp or fiscal marking solution would implement the requirements for the security feature as an authentication element only requiring no link to a fiscal marking / tax stamp programme.

To provide a baseline for comparison, four different security feature options were prepared using 4 distinct scenarios above, and shared with a subset of security feature providers (a sample of respondents of the previous survey conducted as part the primary technology solution providers survey). Further, the four options included some minor variations in specific security feature elements (either for overt, covert or forensic) to facilitate the discussion with security feature providers on package design considerations, potential compatibility considerations and cost implications.

9.1 GENERAL CONSIDERATIONS (ACROSS FOUR OPTIONS)

A number of considerations apply generally to all four options and are discussed further below.

9.1.1 METHOD OF APPLICATION

In addition to the package of security feature elements, a key consideration is the method in which these security features can be applied to each unit of tobacco product. The five methods considered include:

1. Incorporating the security feature as part of the production of the packaging material itself.
2. Including the security feature in a specific element of the packaging that can be controlled (e.g. tear tape).
3. Printing the security feature using security inks directly onto the product.
4. Providing the security feature as self-contained security package as a label, film or stamp.
5. Security feature combined with fingerprinting of unique material properties of the package.

A summary of each of these, together with key advantages and disadvantages, is discussed below.

9.1.1.1 INCLUDING THE SECURITY FEATURE IN THE COMMERCIAL PACKAGING

In this method, the security features are included in the actual cigarette packaging, at the time that the packaging materials are produced (before supply to the tobacco manufacturing process). Commercial printing processes and commercially available security features do not create a technical or cost barrier for potential fraudsters by themselves. To address this, one or two security elements may be provided for the commercial printer to incorporate.

The key advantages of this method:

- Costs controlled as security elements are incorporated as part of packaging production process, with no downstream impact on the tobacco manufacture process.
- This also provides an easy option for some covert and forensic elements to be introduced across multiple areas of the packaging.

However, there are some disadvantages that include:

- Difficulty controlling and auditing all the involved printers and the supply chain of these security elements and/or security inks and the finished printed packaging. Further, it is difficult to maintain control and protection of the secrecy of the security feature.
- Limitation of choice of security elements that can be included, as some security production processes and techniques are not available commercially.
- Generally the processes at non-security printers are less strict and the need for documentation of material balance and waste are less.
- Security features need to be designed to be compatible with a large variety of different printing machines that may be used.

- Variability in the finished result depending on the respective printers, leading to packs on the market with different aspect of the security feature itself.
- Adding security features directly on the tobacco packaging is intrusive for the packaging design and all the brands will have to adapt their designs to incorporate the security feature.

9.1.1.2 INCLUDING THE SECURITY FEATURE IN SPECIFIC PACKAGING ELEMENTS

In this method, elements of the security feature are included in the clear wrap or tear-tape packaging elements.

Key advantages:

- Addresses several of the weaknesses of the commercial packaging option by concentrating the security feature to a specific component, which can be controlled.
- Opportunity to provide some indication of volume information (important for reconciling integrity of the overall tobacco traceability solution discussed in 8.6.12 above).

A disadvantage of using item such as the clear-wrap or tear-tape packaging as a further disadvantage in that most cases it is removable, in conflict with the requirements of Article 16 §1, which requires the security feature to be irremovable from the unit packets of tobacco products. To comply, sections of the overwrap or tear tape would have to be permanently affixed to the tobacco packaging and designed to separate during removal, adding complexity and cost to combat the security element being removed and discarded during pack opening. Alternatively, a second tear tape would need to be applied (not removed during package opening) requiring a second tear tape applicator to be installed on each production line.

9.1.1.3 DIRECT PRINTING OF THE SECURITY FEATURE

This security feature is applied during the tobacco manufacturing process on the product line directly onto the product packaging. The application requires a specialised printer with security ink, and every production line would have to be equipped with a printer (capable of using the security ink), while the consumables have to be treated in a secure and controlled way, similar to the stamp / label option considered below.

The key advantages of this method:

- The security feature is physically printed on the packaging material and cannot be removed and reapplied on another product.
- Opportunity for some volume control (based on volume of security inks used - important for reconciling integrity of the overall tobacco traceability solution discussed in 8.6.12 above).
- Suitable for highly automated production machines.

Disadvantages include:

- Technology constraints limit the designs and flexibility of the security feature. Also, requirements for a defined area of the packaging (colour, size and position) where the security feature is applied may require modification of the design of the packaging of tobacco products.
- The security features are distributed on a volume base and not on an individual base which makes the material balance less precise.

- Method is not appropriate for low volume or non-automated production.
- Installation of such equipment in a production factory can be intrusive and requires adequate legal basis. The installations have to be supported by a maintenance team for on-going equipment and production support.
- Some limitations may be applicable for operation of the solution on production lines outside of the EU where there may be no legal basis to require access and control of the equipment.

9.1.1.4 PROVIDING THE SECURITY FEATURE AS A LABEL OR STAMP

A stamp or label is used to transport/carry the security feature comprising all of the security elements. The stamp or label is produced by a security printer, separate from the commercial processes used to produce the tobacco packaging.

Key advantages of this method:

- Opportunity to include all four security layers (overt, semi-covert, covert and forensic) to improve security value.
- Security printers are used to handle sensitive material like papers, security elements, security inks, semi-finished and finished goods. Certification and compliance requirements require all steps of the production to be documented including material balance, batches, and waste.
- Existing secure supply chain logistics are used for both inputs to the security feature, and control of storage and distribution itself.
- Flexibility and choice of available security elements that can be used because of control of inputs including security papers, inks and features are available to security printers (some security element providers only allow delivery to certified and security printers).
- Similarity to method used for tax stamps means this equipment can be used with existing processes and equipment that can potentially be leveraged.
- The control of stamps during manufacturing process is known and generally accepted. Provides accurate volume verification (important for reconciling integrity of the overall tobacco traceability solution discussed in 8.6.12 above).
- The application of stamps is possible for full scope of manufacturing processes: automated and high volume production lines, imported goods can be labelled at the manufacturing site abroad and low volume production lines can be labelled manually.

Some of the disadvantages include:

- Limitations on the size of the label / stamp, especially if required to be compatible with high-speed label applicators used for tax stamps.
- Requires administration by the manufacturers to manage their quantities of labels / stamps on hand, and to ensure these are stocked in the label applicator equipment ahead of production runs.
- Requires additional station on tobacco production line for application of the label / stamp. Application on the production line places this process on the critical path, and any label /stamp defects or problems create the risk of causing production downtime.
- Stamps and labels require additional measures to prevent removal and reapplication. This is critical as the security features provide assurance that the stamp / label is genuine, though this is only effective if its affixed to the tobacco product in a manner that ensures that assurance is transferrable to the product.

9.1.1.5 COMBINING THE SECURITY FEATURE WITH FINGERPRINTING

Intrinsic properties of the material of the tobacco product packaging (the material itself or “random” variations in printed elements), that are unique and near impossible to replicate, are recorded and stored, allowing a tobacco product to be checked for authenticity at a later time to determine if in fact it is the same product.

The security technique of material fingerprinting does not of itself provide a security package with overt elements, but depending on implementation, the acquisition process is inherently a consideration of how the security feature is applied to the tobacco product, and how it can be combined with security elements.

Key advantages of this method:

- Provides a very strong covert security element.
- Robust method for authentication of the tobacco product packaging itself (thereby addressing issue of labels / stamps that may be reused).
- By independently storing the repository of acquired tobacco products, provides accurate volume verification (important for reconciling integrity of the overall tobacco traceability solution discussed in 8.6.12 above).

Disadvantages include:

- Expected higher implementation costs as a result of equipment required for acquiring and determining a unique identification record for each item that can be stored and retrieved, with required operation of the associated repository.
- Some impact on the packaging design process to ensure compatibility of the specific area that is fingerprinted, and enrolls these designs so the solution can identify reference elements required for the acquisition process.

9.1.1.6 METHOD OF APPLICATION USED FOR THIS ASSESSMENT

In the preparation of the four options for security features, the choice of providing the security feature as a label / stamp, with the further consideration of using fingerprinting techniques, was used as the basis for analysis for the following reasons:

- The limited security of using commercial printing techniques was considered a weakness for production of a security feature intended to aid efforts to combat counterfeit or falsified products.
- Using clear wrap or tear tape packaging elements did not readily meet the requirements for an irremovable security feature
- The secure label / stamp provided additional implementation flexibility, choice of security elements and compatibility with both high speed and low volume tobacco production volume over direct marking.

Of the four options for security features below, an option specifically integrating a fingerprinting security technique is included for assessment purposes.

9.1.2 ESTABLISHING SECURITY BEYOND THE SECURITY FEATURE

The effectiveness of a security programme depends on how difficult it is to replicate the given features and how secure the supply chain is. The protection of the security feature extends beyond the sophistication of the security elements themselves, but also requires consideration of the secure production and distribution of the security feature to the point of application.

In response to the growth in international crime and illegal immigration, and the increasing concerns over the security of travel documents, the International Civil Association Organisation has published a set of “recommended minimum security standards” as a guideline for all States issuing machine-readable travel documents (Passports and Visas). The security standards for Document 9303¹¹⁷, recommends several controls that are implemented as a baseline that would similarly be relevant for the security feature described in Article 16, and these include:

- Production should take place in a secure, controlled environment with appropriate security measures in place to protect the premises against unauthorised access.
- Establishing controls for full accountability over the security materials used in the production of the security feature. This should include a full reconciliation at each stage of the production process with records maintained to account for all security material usage. The audit trail should be to a sufficient level of detail to account for every unit of security material used in the production and should be independently audited by persons who are not directly involved in the production.
- Records should be certified at a level of supervision to ensure accountability should be kept of the destruction of all security waste material and spoiled security feature items.
- Materials used in the production of the security feature should be of controlled varieties where applicable, and obtained only from reputable security materials suppliers. Materials whose use is restricted to high security applications should be used, and materials that are available to the public on the open market should be avoided.
- Sole dependence upon the use of publicly available graphic design software packages for originating the security feature graphic design should be avoided. These software packages may however be used in conjunction with specialist security design software.
- Knowledge of the covert security feature elements should be restricted and disclosed on a “need-to-know” basis.

The following recommendations are provided for consideration in the case of all four options:

- Whilst Option 4 considers the addition of a unique identifier to the security feature, its recommended that at least basic serialisation of the security feature is considered for the other three options as well. This provides the basis for controls and accountability for possession of the security feature elements.
- Further, a control system should be in place in accordance with security printing standards (such as ISO14298:2013(E) Management of Security Printing Processes, NASPO certification) for risk management and control of the security feature elements.

9.1.3 SECURITY FEATURE ROTATION AND RISK OF COUNTERFEITING

It is recommended that the security feature be reviewed every three to five years, (minimum every five years) to evaluate the security elements used to create the security features.

Market evidence that the security feature (or particular elements) has been compromised in significant volumes would necessitate an earlier review. For this reason, it is

¹¹⁷ ICAO Document 9303, Final Release 14, Date: May 13 2014

recommended that a backup design be prepared to be ready for immediate reaction to such evidence.

Increasing the frequency of changes to the security feature can be negative because of public training and change over cost implications associated with input materials, inventory and changes to business processes. Further, each period of transition (and associated lack of familiarity with the revised security feature elements) provides a potential window of opportunity for counterfeiters.

9.1.4 SAFE FOR USE ON TOBACCO PRODUCTS

The components of the security feature need to be safe for application to tobacco products, which are destined for human consumption. Therefore, all materials, including paper, ink, taggants and glues required for implementation need to consider basic health safety.

9.1.5 ECONOMIES OF SCALE AFFECTING PRODUCTION

Security features produced by security printers generally benefit from significant economies of scale advantages. This results from the high costs associated with the configuration and setup for a print run, while the print run itself is generally a continuous process. However, these economies of scale do have a limit as the production capacity of the security printer is reached. Therefore, as an indication, economies of scale advantages may already be realised as batch sizes are increased to 2 billion pieces, with diminishing further returns as this is increased beyond 3-5 billion security feature pieces.

Therefore, strategic procurement / sourcing by the EU Member States should be considered to maximise this cost advantage.

Therefore, it is envisaged that consolidating production of security features for the collective EU market is unlikely to yield any significant cost advantage over larger Member States sourcing individually. Conversely, for those EU Member States with lower volume requirements, there may be an incentive to pool security feature sourcing to attain the security feature advantages.

9.1.6 FLEXIBILITY TO ACCOMMODATE THE VARIETY OF TOBACCO PACKAGING

It is recommended that some flexibility for the label application method is allowed to accommodate the varieties of packaging types, and the mix of production processes associated with tobacco products in the EU that spans very high volume automated cigarette pack manufacture through to specialty low volume and hand packaged tobacco items.

Self-adhesive has a higher unit cost, but is more flexible in terms of application location and method (automated application or application by hand). Further, the self-adhesive backing is a production waste item that requires removal. Self-adhesive labels can therefore accommodate a greater variety of packaging types, automation and low volume manufacturing runs.

Security features provided as dry labels have a cost advantage, but require label applicators that apply glue to the label before application to the tobacco items. This makes it suitable for large volume manufacture. These dry labels are either provided in reels or in stacks.

9.1.7 SECURITY FEATURE SIZE

There are two important considerations related to sizing: the size of the security feature label in its entirety (e.g. 20mm x 44mm as a typical size used by a tax stamp), as well as the size of the individual security elements on the security feature (e.g. hologram of 10mm x 10mm).

Considering the security feature requirements of the TPD, and the requirement for this to be used across a variety of tobacco products, including small tins such as chewing tobacco, the feasibility of a smaller security feature 10mm x 15mm was investigated as part of a follow up survey to a subset of security feature providers of the original survey. General feedback raised several concerns related to the use of the smaller security feature size:

- Limitations on the design of the security feature, with the challenge of including all the required security layers on the small size (e.g. allowing the required safe zone around cutting – would only allow a hologram of a maximum width of 8mm with reduced effectiveness as a security element).
- Possibility to apply a security feature of this size using applicators on the production line. Further, a size outside the capabilities of current applicators is anticipated to increase the cost of these items with potential reliability impacts adversely affecting production line performance.
- Some challenges in the production of the security feature itself, associated with the cutting machine (used to cut the security features to size and bundle in 1000 piece stacks).

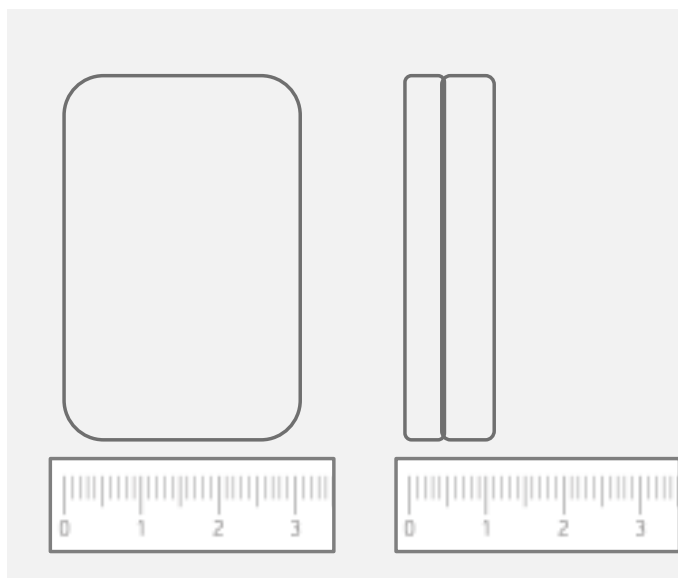


Figure 50 - Compact dimensions of chewing tobacco in tins create size constraint for security feature

It is therefore recommended that a mix of security feature sizes be specified for different categories of tobacco products. Where stamps / labels are used for high speed cigarette manufacturing lines, compatibility with existing label applicators size requirements is anticipated to provide both a reliability and cost advantage.

9.1.8 SECURITY FEATURE PLACEMENT ON THE TOBACCO PRODUCT

The following considerations relate to the placement of the security feature on the tobacco product units:

- As indicated in Article 16, the security feature should be irremovable, and therefore applied directly to the tobacco pack, and under any clear wrap materials, so that even opened or discarded packs can be checked for authenticity;
- Placement under the clear wrap also provides a level of protection to the security feature during transport;
- It is recommended that the security feature is placed in such a manner over the tobacco pack opening (for both soft packs and flip-top style packs), in so far as this is possible, to ensure that a portion is damaged during pack opening, to prevent potential reuse of the security feature on illicit packs.
- Placing the security feature near the top of the pack where it will not be obscured by retail stands also allows quick visual inspection that displayed stock is compliant. It also creates a psychological deterrent that trading non-conformant products is wrong and visible – not only by law enforcement officials, but by fellow consumers and the general public.

9.2 SECURITY FEATURE: OPTION 1

Authentication features used for tax stamps suitable for tobacco products provide a useful foundation for the assessment of security features relevant to TPD Article 16. There are several shared objectives between the security feature requirements and tax stamps in operation today, which are considered below:

- Tax stamps have evolved to include security features for authentication by different user groups, 1) provide a reliable overt mechanism for consumers and members of the public, and, 2) provide additional covert features suitable for enforcement agencies.
- Need to be resistant to attempts at manipulation, imitation and reproduction.
- Technologies and application methods need to be suitable for tobacco products and generally should minimise impact on tobacco manufacturers
- Fulfil requirements of government stakeholders, beyond the brand protection of the tobacco manufacturer; and
- Need to be cost effective.

Therefore, taking these into account, the specifications for the security feature package for the first option is drawn from an example of a modern tax stamp specification cited in an industry Tax Stamp technical study report¹¹⁸. This was used as an initial basis to establish the required four levels of authentication. The specification has been adapted to provide additional flexibility for either an optically variable device or an optically variable ink to improve flexibility for the assessment.

¹¹⁸ Tax Stamps: A Technical Study and Market Report. Reconnaissance International. 2012. "Tax Stamp Production and Authentication: Bringing it all Together – Kenya's recently issued tax stamp tender"

Option 1	
Level 1 (Overt)	<ul style="list-style-type: none"> Optically Variable Device (Option 1A) or Optically Variable Ink (Option 1B) Overt Guilloche Pattern (Security Print Technique)
Level 2 (Semi-Covert)	<ul style="list-style-type: none"> Micro text UV inks with bi-fluorescence reaction Covert Holographic Feature (1A) or Semi-covert Ink Effect (1B)
Level 3 (Covert)	<ul style="list-style-type: none"> Laser or Machine Readable Taggant
Level 4 (Forensic)	<ul style="list-style-type: none"> Forensic Marker
Tamperproof	<ul style="list-style-type: none"> Frangible Paper and adhesive Die cuts (Kiss cuts) for self-adhesive labels
Paper	<ul style="list-style-type: none"> Frangible paper, tax stamp quality suitable for use in high speed label applicators (dry labels)
Application Method	<ul style="list-style-type: none"> Dry Label and Self Adhesive label Available as stacks or reels to suit manufacturers preferences

Table 38 - Security Feature - Option 1

This option proposes that the security feature is applied to tobacco packs by means of a dry label (primarily for cost control purposes) that would be suitable for high-speed application on cigarette manufacturing lines, and self-adhesive labels suitable for other tobacco products (e.g. pouches or hand-packed cigars).

9.2.1 ANALYSIS OF THE IMPLICATION FOR INTRODUCTION IN THE EU

The assessment of Option 1 of the security feature considers the following practical aspects:

Lead Times for Project Start	<ul style="list-style-type: none"> Typically from agreement of a security feature design, working inventory of security features could be supplied to tobacco manufacturers within 8-12 weeks. However, because Option 1 includes a machine-readable taggant, it is anticipated an additional 8-12 week lead-time would apply for development purposes.
Implementation Considerations	<ul style="list-style-type: none"> The paper used and finished labels and stamps should be tested by manufacturers for use in the high-speed label applicators.
Availability of Capable Providers	<ul style="list-style-type: none"> It is anticipated that there are no feasibility issues related to Option 1, with a wide variety of capable security solution providers able to supply a security feature meeting these requirements. It should be noted that there are very few suppliers of optically variable ink. This has the advantage that it reduces the ability for this security element to be replicated, but simultaneously has the disadvantage of reducing the available sources for this component. As a result, the cost of such security inks is quite high, making it equivalent to the price of an optically variable device (OVD).

Suitability for Tobacco Product Packaging	<ul style="list-style-type: none"> ▪ This option includes several security elements already used on tax stamps applied to tobacco products today. Therefore there are no expected feasibility issues for the use of Option 1 on tobacco packaging.
Ordering and Delivery Logistics	<ul style="list-style-type: none"> ▪ Tax stamp ordering and logistics processes that provide control of labels / stamps of value are currently established and in operation in most Member States today and can serve as a model for security features. Manufactures operating in the EU would already be familiar with such processes, receipting, storage and waste management of these elements. ▪ It is anticipated that as the distribution model has already been proven, that the logistics infrastructure could be setup in those four Member States that do not currently have tax stamp programmes.
Application to Tobacco Products	<ul style="list-style-type: none"> ▪ The secure labels / stamps will be applied to tobacco product units using label applicators suitable for medium and high-speed highly automated production lines. For cost control purposes, the glue is applied to the stamp / label on the production line as part of the application process. ▪ For manual non/automated production lines, the security feature can be supplied as a self-adhesive label, and applied using a line label applicator, handheld applicator or by hand (and for sensitive tobacco products).
Authentication Effectiveness	<ul style="list-style-type: none"> ▪ It is anticipated that the security feature package and application method could provide a mechanism for a clear overt, covert and forensic authentication result.
Field Inspection Support	<ul style="list-style-type: none"> ▪ This security feature package will require the following for authentication devices: <ul style="list-style-type: none"> ○ Level 2: UV Torch (handheld UV light source of required wavelength¹¹⁹) → Provided to EU and Member State Officials (e.g. Police, Customs Officers, Excise Officers). ○ Level 2 (1A): Simple Magnifying lens → provided for Distribution Chain Economic Operators. ○ Level 2 (1B): Card filter for authenticating the polarising lens effect / polarised light torch → Provided for Distribution Chain Economic Operators. ○ Level 3: Taggant Reading device (tests for the presence of the taggant and provides a yes/no authentication result) → Provided for EU and Member State officials working specifically in the area of Tobacco control, surveillance or law enforcement.
Forensic Support	<ul style="list-style-type: none"> ▪ Security feature provider should indicate available laboratory capacity for forensic analysis to support enforcement case development. It is expected that in addition to the forensic marker, elements of the paper, printing method and laboratory analysis of the overt security element (1A and 1B) will enable a clear authentication result.

¹¹⁹ UV inks can contain materials that fluoresce under specific wavelength bands of UV light. Further, different materials may fluoresce into different colours in the visible light spectrum, therefore allowing different response colours (such as red, blue, green, etc) to be revealed under a UV light emitting the necessary wavelength. Therefore as an example, authorities may be provided with flashlight emitting a specific band of UV light which reveals the security feature.

Education Requirements

- Consumer education on use of the overt security elements is considered feasible, as both proposed options (1A and 1B) are considered elements with which consumers would already be familiar on items such as currency, government documents and brand protection features.
- In order to encourage pro-active assessment, distribution chain operators should be provided with affordable semi-covert authentication devices (magnifiers [Option 1A] or polarising filters [Option 1B]). It is anticipated that awareness training of the feature would be sufficient for stakeholders to authenticate with minimal practice.
- Education for enforcement officials will be required on the use of field devices for authenticating the covert elements. However, this is expected to be minimal (requiring exposure to the technology with the opportunity for some practice using the devices) as authentication devices typically provide a clear (yes/no) authentication result.

In the event of counterfeiting, several elements of the package could be quickly adjusted as necessary:

- Optically Variable Ink (Option 1B) colour effects can be changed to a different colour range;
- Bi-fluorescent ink light wavelength response can be adjusted to increase security in need;

9.2.2 ADVANTAGES AND DISADVANTAGES

Advantages of Option 1:

- Provides a competent mix of security feature elements with similar security value and cost as current tax stamps / labels.
- Multiple security element layers (overt, covert and forensic) increase the difficulty for security feature to be counterfeited.
- Supply and application of the security feature is compatible with established processes and equipment currently used for tax stamps.

Disadvantages of Option 1:

- The disadvantages of using a label / stamp apply as the carrier method as identified in 9.1.1.4 above.

9.2.3 COMPATIBILITY WITH CRITICAL SOLUTION FACTORS

1	Provide a reliable mechanism to authenticate the legitimacy of the product (Article 16, §1);	☑
2	Have overt elements which provide the modicum of authentication by the consumer without requiring specialised equipment / devices (Article 16, §1 and impact assessment considerations);	☑
3	Must be tamper proof and irremovable (Article 16, §1);	☑
4	Ensure that covert elements are accessible by authorised persons and protect commercially sensitive data, if necessary (article 16, §1 and impact assessment considerations);	☑
5	Provide court-admissible forensic evidence of security feature authentication;	☑

6	As far as possible, be compatible with current tobacco production, packaging trade environment and existing tax regimes and avoid unnecessary burden for business and/or authorities (internal market proportionality obligations).	<input checked="" type="checkbox"/>
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9.3 SECURITY FEATURE: OPTION 2

The tobacco industry proposed solution suggests using serialisation (tobacco traceability solution) as the means to determine if a tobacco product is legitimate and propose that the unique identifier is visible and therefore provides an overt security element. However, verification using the unique identifier alone provides poor authentication, as the result does not confirm whether a unique identifier has been copied. It only provides confirmation that the unique identifier is valid (and has not been verified previously), but does not provide assurance that the tobacco product is legitimate. Further, using a smartphone or mobile device makes this a semi-covert security feature, but provides no overt, strong covert or forensic features.

As outlined in ISO16678: 2014(E), "Guidelines for interoperable objective identification and related authentication systems to deter counterfeiting and illicit trade" which considers common frauds, physical security layer options adjacent to the unique identifier include (but are not limited to) security papers, inks, taggants, optically variable devices and other authentication features).

The security package Option 2 therefore proposes a number of security elements that can be used to authenticate the tobacco product, that supplement the unique identifier that may be applied using direct marking methods as considered in the traceability options 1, 2, or 3 to create a competent package for authentication by both consumers and law enforcement officials. In other words, option 2's security package is overall slightly weaker than security feature option 1 (it does not include a semi-covert element), but would still supplement the unique identifier applied to each pack, as required by Article 15.

Option 2	
Level 1 (Overt)	<ul style="list-style-type: none"> ▪ Optically Variable Device (Option 1A) or Optically Variable Ink (Option 1B) ▪ (Optional) Iridescent ink or foil
Level 2 (Semi-Covert)	<ul style="list-style-type: none"> ▪ Use Track and Trace Serialisation (using traceability options 1, 2 or 3)
Level 3 (Covert)	<ul style="list-style-type: none"> ▪ Laser or Machine Readable Taggant
Level 4 (Forensic)	<ul style="list-style-type: none"> ▪ Forensic Marker
Tamperproof	<ul style="list-style-type: none"> ▪ Frangible Paper and adhesive ▪ Die cuts (Kiss cuts) for self-adhesive labels
Paper	<ul style="list-style-type: none"> ▪ Frangible paper, tax stamp quality suitable for use in high speed label applicators (dry labels)
Application Method	<ul style="list-style-type: none"> ▪ Dry Label and Self Adhesive label ▪ Available as stacks or reels to suit manufacturers preferences

Table 39 - Security Feature - Proposed Option 2

This option proposes that the security feature is applied to tobacco packs by means of a dry label (primarily for cost control purposes) that would be suitable for high-speed

application on cigarette manufacturing lines (it is frequent feature of these devices to apply adhesive during the application process), and self-adhesive labels suitable for other tobacco products (e.g. pouches or hand-packed cigars) suitable for application using automated applicators, hand applicators or manually.

9.3.1 ANALYSIS OF THE IMPLICATION FOR INTRODUCTION IN THE EU

The primary difference between Option 1 and Option 2 relates only to the use of the unique identifier and capability to use this for tracing purposes to supplement the authentication features. It is therefore anticipated that the same implications will be relevant as those identified for Option 1 above (9.2.1), with the additional requirement for tobacco traceability application and / devices as considered in 8.6.10 above, that would be required to supplement the authentication process.

9.3.2 ADVANTAGES AND DISADVANTAGES

Advantages of Option 2:

- Provides a competent mix of security feature elements with similar security value and cost as current tax stamps / labels.
- Multiple security element layers (overt, covert and forensic) increase the difficulty for security feature to be counterfeited.
- Supply and application of the security feature is compatible with established processes and equipment currently used for tax stamps.

Disadvantages of Option 2:

The disadvantages of using a label / stamp apply as the carrier method as identified in 9.1.1.4 above.

9.3.3 COMPATIBILITY WITH CRITICAL SOLUTION FACTORS

1	Provide a reliable mechanism to authenticate the legitimacy of the product (Article 16, §1);	☑
2	Have overt elements which provide the modicum of authentication by the consumer without requiring specialised equipment / devices (Article 16, §1 and impact assessment considerations);	☑
3	Must be tamper proof and irremovable (Article 16, §1);	☑
4	Ensure that covert elements are accessible by authorised persons and protect commercially sensitive data, if necessary (article 16, §1 and impact assessment considerations);	☑
5	Provide court-admissible forensic evidence of security feature authentication;	☑
6	As far as possible, be compatible with current tobacco production, packaging trade environment and existing tax regimes and avoid unnecessary burden for business and/or authorities (internal market proportionality obligations).	☑

9.4 SECURITY FEATURE: OPTION 3

This security package option considers using an emerging technology to record a surface fingerprint of a specific area of the tobacco packaging for each tobacco product to create

a repository of trusted items that can be referenced during the subsequent authentication process.

As these technologies require a device for authentication, an additional overt security feature has also been combined to augment the security package. While some fingerprinting techniques may have specific requirements of the material being fingerprinted, some solutions have established that the paper substrate alone can be sufficient, and introduces flexibility as to whether an area of the packaging of the tobacco product itself, a label or tax stamp is used.

Option 3 below therefore proposes a package of security elements that uses fingerprinting to provide the authentication element for semi-covert and covert levels. The fingerprint is acquired from a section of the tobacco pack / item directly. As fingerprinting does not provide overt security features, a label / stamp is used in this option for the purposes of the overt and forensic security elements.

Option 3	
Level 1 (Overt)	<ul style="list-style-type: none"> ▪ Optically Variable Device (Option 1A) or Optically Variable Ink (Option 1B)
Level 2 (Semi-Covert)	<ul style="list-style-type: none"> ▪ Fingerprinting Technology
Level 3 (Covert)	<ul style="list-style-type: none"> ▪ Fingerprinting Technology
Level 4 (Forensic)	<ul style="list-style-type: none"> ▪ Forensic Marker
Tamperproof	<ul style="list-style-type: none"> ▪ Frangible Paper and adhesive ▪ Die cuts (Kiss cuts) for self-adhesive labels
Paper	<ul style="list-style-type: none"> ▪ Frangible paper, tax stamp quality suitable for use in high speed label applicators (dry labels)
Application Method	<ul style="list-style-type: none"> ▪ Dry Label and Self Adhesive label ▪ Available as stacks or reels to suit manufacturers preferences

Table 40 - Security Feature - Proposed Option 3

9.4.1 ANALYSIS OF THE IMPLICATION FOR INTRODUCTION IN THE EU

The table below considers the implications specifically related for the fingerprinting element. As Option 3 uses a label / stamp, the implications below should also be read in conjunction with those identified in Option 1 in section 9.2.1 above.

<p>Implementation Considerations</p>	<ul style="list-style-type: none"> ▪ Each production line will need to be fitted with an enrolment device that will be used to record the pack fingerprint during the production process. ▪ The fingerprint result should be recorded with the unique identifier of the pack (to address risk of fingerprinting algorithm potentially restoring the same fingerprint result from two different items). ▪ This will require some intrusion on the tobacco production lines, as well as a secure area on the manufacturing premises for installation of server and storage equipment. The enrolled fingerprint information is stored on this server at the manufacturing site (also provides a backup storage mechanism should connectivity be temporarily unavailable) and then uploaded to a central server. ▪ Similar to Traceability Option 2, Security Feature Option 3 will require a legal basis for the security solution provider to have access to manufacturing premises for equipment installation, maintenance and support.
<p>Availability of Capable Providers</p>	<ul style="list-style-type: none"> ▪ It should be noted that to date this is an emerging field, and as a result there are few technology solution providers currently available. ▪ Further, implementation success should be demonstrated to establish that the technology can operate at full production speeds typical of the tobacco industry (1,000 packs per minute).
<p>Suitability for Tobacco Product Packaging</p>	<ul style="list-style-type: none"> ▪ The finger printing process requires some consideration of the tobacco packaging design (to identify an element of the packaging where there is a static element that can be used as a reference point to ensure that same area is sampled as part of the fingerprint). ▪ The solution therefore typically requires an enrolment charge, a fee charged by the security feature solution provider for each tobacco package design that is configured to work with the finger printing solution. Similarly this enrolment process and fee would be charged when tobacco packaging designs are changed or amended.
<p>Ordering & Delivery Logistics</p>	<ul style="list-style-type: none"> ▪ As a digital solution, there are no ordering, delivery or logistic components for those tobacco products that can be finger printed directly on the manufacturing line (anticipated to be majority of EU market tobacco products for cigarettes and roll your own tobacco). ▪ For low volume / non-automated tobacco producers where fitment of an on-production line enrolment device, an alternative solution may be to fingerprint the label / stamp used for the over security feature. Order and delivery would follow typical tax stamp control processes. For these small / low volume producers, the pre-enrolled stamps / labels could be provided to these producers and applied using label applicators, handheld applicators or manually.
<p>Authentication Effectiveness</p>	<ul style="list-style-type: none"> ▪ Option 3 security feature provides strong covert authentication element that the tobacco packaging being authenticated is the same tobacco package enrolled at the time of manufacture. Directly on the packaging itself, this covert element can therefore not be removed and transferred to another product. ▪ The proposed label / stamp provides a clear overt, and forensic authentication result.

Field Inspection Support	<ul style="list-style-type: none"> ▪ Authentication of the tobacco product using the covert security element requires a mobile reading device or desktop-connected reading device, typically dedicated for this purpose. ▪ Knowledge of the area to be checked is required for a successful authentication result (to ensure that the same area of the packaging is matched against the area of the packaging that was enrolled during the initial finger-printing process).
Education Requirements	<ul style="list-style-type: none"> ▪ Some training on use and operation of the field devices for authenticating the covert elements will be required. ▪ Some additional training on the authentication process, as well as reference areas may be required.

Note: Capturing physical properties of an item and creating a digital signature that allows the same item to be authenticated in the future, provides an innovative mechanism that avoids the need to add additional material elements. Storing the digital signature in a database does introduce a dependency on an online network connection at the time of the subsequent authentication, as the 2nd fingerprint results needs to be verified against the initial fingerprint to confirm the item is indeed the same.

A potential alternative implementation might involve recording the fingerprint “signature” on the item itself (e.g. printed in a machine readable code on the product itself). However, caution is advised when considering this approach, however, as it circumvents one of the inherent controls of the security feature that can support verification of the correct operation of the traceability solution. By designing the authentication process where the digital “signature” of fingerprint is stored, EU and Member State authorities automatically are able to tally the number of items fingerprinted (and therefore can be validated as an authentic product). Any potential compromise of the fingerprinting algorithm does not necessarily compromise the items already fingerprinted or enable further additional exploitation of the solution. However, by using a method of storing the result on the item, in the event the finger printing algorithm is compromised, authorities would not receive any indication that there are illicit products on the internal market that incorrectly would be authenticated as legitimate.

9.4.2 ADVANTAGES AND DISADVANTAGES

Advantages of Option 3:

- Fingerprinting an area of the tobacco packaging itself provides an incredibly strong level of authentication, and when the acquired fingerprint is stored and linked with the unique identifier of that particular package (applied at time of manufacture / finishing as per **traceability option** 1, 2 or 3, or during production of the security feature in **traceability option** 4), can be used to validate that the item / pack being authenticated is the same item / pack that was enrolled at the time of production.
- By validating the fingerprint signature against the database of enrolled signatures that are associated with each unique identifier, the system provides a control check of how many items have been enrolled (and would therefore pass the authentication check) which is systematically reconciled against the number of items marked for traceability purposes.
- There is no trace of the area fingerprinted, making analysis and reproduction near impossible.

Disadvantages of Option 3:

- Some intrusion on manufacturing lines for installation of the enrolment devices.
- Cost of capital equipment required on each production line.
- Low number of available solution providers able to implement this solution.

9.4.3 COMPATIBILITY WITH CRITICAL SOLUTION FACTORS

1	Provide a reliable mechanism to authenticate the legitimacy of the product (Article 16, §1);	☑
2	Have overt elements which provide the modicum of authentication by the consumer without requiring specialised equipment / devices (Article 16, §1 and impact assessment considerations);	☑
3	Must be tamper proof and irremovable (Article 16, §1);	☑
4	Ensure that covert elements are accessible by authorised persons and protect commercially sensitive data, if necessary (article 16, §1 and impact assessment considerations);	☑
5	Provide court-admissible forensic evidence of security feature authentication;	☑
6	Be compatible with current tobacco production, packaging trade environment and existing tax regimes and avoid unnecessary burden for business and/or authorities (internal market proportionality obligations).	☑

9.5 SECURITY FEATURE: OPTION 4

This security feature package is prepared as a competent authentication mechanism, with the further consideration to leverage potential synergies with the traceability solution. This is enabled by including a secure machine-readable serialisation code in the security package that can be used as a basis for the unique identifier.

For some Member States that already have tax stamps or national identification markings for fiscal purposes, there may be further synergies and cost savings realised by combining the requirements in Option 4.

This proposed option includes similar security feature elements as Option 1, **with the addition of a machine readable unique code applied** to each security feature.

Option 4	
Level 1 (Overt)	<ul style="list-style-type: none"> ▪ Optically Variable Device (Option 1A) or Optically Variable Ink (Option 1B) ▪ Overt Guilloche Pattern (Security Print Technique)
Level 2 (Semi-Covert)	<ul style="list-style-type: none"> ▪ Micro text ▪ UV inks with bi-fluorescence reaction ▪ Covert Holographic Feature or Semi-covert Ink Effect
Level 3 (Covert)	<ul style="list-style-type: none"> ▪ Laser or Machine Readable Taggant
Level 4 (Forensic)	<ul style="list-style-type: none"> ▪ Forensic Marker
Tamperproof	<ul style="list-style-type: none"> ▪ Frangible Paper and adhesive ▪ Die cuts (Kiss cuts) for self-adhesive labels
Paper	<ul style="list-style-type: none"> ▪ Frangible paper, tax stamp quality suitable for use in high speed label applicators (dry labels)
Application Method	<ul style="list-style-type: none"> ▪ Dry Label and Self Adhesive label ▪ Available as stacks or reels to suit manufacturers preferences

Table 41 - Security Feature - Proposed Option 4

For this option, the machine-readable code has been proposed as a visible marking. Additional data such as security feature producer, date and time and product category may be incorporated as part of the unique identifier. As the traceability information is intended primarily for law enforcement officials, rather than consumers, this information should be secured and only accessible to authorised parties. The option of printing the unique identifier in an invisible ink does add a further level of security, but has the consequence of only allowing the unique identifier to be read by specialised equipment, and will therefore require consideration as to whether this additional security is worth the inconvenience.

This option proposes dry labels for cost control purposes, though the option for self-adhesive labels can also be included as part of the evaluation.

9.5.1 ANALAYSIS OF THE IMPLICATION FOR INTRODUCTION IN THE EU

This solution uses the same security features as Option 1 for comparison purposes. Therefore, the same implications identified for Option 1 are anticipated to apply for Option 4 related to label / stamp and the security elements themselves, with the following additions.

Implementation Considerations	<ul style="list-style-type: none"> ▪ The security printer will be responsible for the generation of the unique identifier and application of this to the label / stamp. This will require coding equipment and printers for adding this variable data to be installed at the security printer site. ▪ For security control purposes, the unique identifiers generated and printed should at that point be uploaded to the traceability data repositories, as a record of the security labels produced. ▪ To ensure readability of the unique identifier on the production line, a vision system, or other validation system, for quality control purposes should be installed on the security printing lines to ensure readability.
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Availability of Capable Providers	<ul style="list-style-type: none"> ▪ It is anticipated that there are no feasibility issues related to Option 4, with a wide variety of capable security solution providers able to supply a security feature meeting these requirements.
Suitability for Tobacco Product Packaging	<ul style="list-style-type: none"> ▪ This option includes several security elements already used on tax stamps applied to tobacco products today. Option 4 is therefore anticipated to be fully feasible for application on tobacco products.
Ordering & Delivery Logistics	<ul style="list-style-type: none"> ▪ Tax stamp ordering and logistics processes that provide control of labels / stamps of value are currently established and in operation in most Member States today. ▪ It is anticipated that the unique identifier on the security feature itself will allow batch tracking of these from the security printer to the manufacturers, providing the potential for stock and security control. ▪ Further, lost, damaged or stolen security features can be recorded and identified by means of the unique identifier.

As with Option 1, in the event of counterfeiting, several elements of the package could be quickly adjusted as necessary:

- Optically Variable Ink (Option 1B) colour effects can be changed to a different colour range;
- Bi-fluorescent ink light wavelength response can be adjusted to increase security in need.

If the unique identifier added to the security feature is decentralized from the security printer production facilities, then appropriate precautions should be taken when transporting the non-coded security feature elements to safeguard their security in transit and storage on arrival. However, this approach is strongly discouraged, and it is recommended that personalization takes place at the same premises. In this way, the unique identifier applied to each security feature becomes an identifier to track the events of the subsequent distribution of the security feature to tobacco manufacturers.

9.5.2 ADVANTAGES AND DISADVANTAGES

Advantages of Option 4:

- The application of a unique identifier to each security feature enables the security feature to be controlled and tracked from the point of secure production, through the order, assignment and distribution process to the point of the tobacco manufacture (and in fact thereafter from application to the tobacco product and through the subsequent tobacco traceability process).

Disadvantages of Option 4:

- Adding the variable data to each unique identifier increases the cost over the base security Option 1¹²⁰.

¹²⁰ Feedback from service providers provide an indicative additional cost component – see 11.4.3 below.

9.5.3 COMPATIBILITY WITH CRITICAL SOLUTION FACTORS

1	Provide a reliable mechanism to authenticate the legitimacy of the product (Article 16, §1);	☑
2	Have overt elements which provide the modicum of authentication by the consumer without requiring specialised equipment / devices (Article 16, §1 and impact assessment considerations);	☑
3	Must be tamper proof and irremovable (Article 16, §1);	☑
4	Ensure that covert elements are accessible by authorised persons and protect commercially sensitive data, if necessary (article 16, §1 and impact assessment considerations);	☑
5	Provide court-admissible forensic evidence of security feature authentication;	☑
6	As far as possible, be compatible with current tobacco production, packaging trade environment and existing tax regimes and avoid unnecessary burden for business and/or authorities (internal market proportionality obligations).	☑

9.6 HIGH LEVEL CONCLUSIONS

Some overall high level points to take note of following the analysis of the four different security feature options are:

- There are a considerable number of overt, covert and forensic security elements that can be combined to create a competent security feature as contemplated in Article 16.
- The confidential nature of the security feature industry made access to specific information difficult. The project relied therefore on general information and was not able to obtain sub-component costs due to the proprietary nature of this information. Direct engagement with security feature providers would ameliorate this within the context of a commercial engagement or public tender.
- There are numerous covert security feature options that can be considered suitable for the invisible component of the security feature. In contrast, there are limited options for an effective overt (visible) security element that enables authentication of the security feature using sight / touch, and without a device.
- While there is considerable flexibility in combining security elements (overt, covert and forensic) to create a security package, there are some interrelationships between the production processes used to create the security feature that can reduce the cost of the overall security feature.
 - As an example, a choice of a particular overt security feature may require a particular process (such as a printing technique). Given that that printing technique is being used for the overt element, it might only require a small incremental cost to include a second security element (for example a covert element), given that the printing technique is already being used.
 - Therefore, during the design process of the security feature, it would be prudent to conduct some engagements with potential security feature producers and determine where cost optimisations acceptable to the EU Commission could be made.
- For several security elements, choice of providers is very limited, in an industry where secrecy and trust is important, there appears to be a practice of well-established relationships between “trusted” providers. This was found to be the case for several security components, including security inks, security foils, and security paper. Similarly in the case of emerging technologies such as fingerprinting, there are again limited solution providers.

10 DATA STORAGE CONTRACTS

The following section outlines an assessment of the requirements related to the data storage contracts with an independent third party. This includes a review of estimated solution data sizes, the storage location implications, and key considerations for the contracts (including audit and service requirements, and proposed terms of reference).

10.1 DATA SIZING CONSIDERATIONS AND STORAGE LOCATION IMPLICATIONS

While reviewing the current four traceability options, the following issues were considered:

1. Data storage requirements; and
2. Compliance costs to traceability solution practicality of implementation with multiple solution providers

An examination of these elements, detailed below, suggests that:

- Data size is not an impediment to the selection of a sole source supplier of data storage (e.g., estimated data for one year = +/-three terabytes).
- Compliance for Manufactures, EU Member States and suppliers would be significantly simplified if storage and processing of data occurred at a single site.
- The use of a single repository for storage of traceability data and processing would ensure compatibility of data sets, reduce the complexity of information assembly and help ensure overall data quality and integrity.
- From a data storage perspective, it is anticipated that operating a traceability solution at pack level would be technically feasible.
- Selection of a single data storage and processing provider would appear to be the easiest to implement, while also being the easiest to administer and the most cost effective (e.g., the cost of conducting 28 separate tenders for Member State level storage would far exceed the cost of data storage with a single provider). The EU is a developed economy with multiple and redundant data and telecommunication links. Given the size of the data sets in question, a single point, on-line Data Management Provider is economically sensible, supports data integrity and is a practical real-time solution.

10.1.1 DATA STORAGE REQUIREMENTS

During our technology survey, two data storage estimates were received from different manufactures, based on current implementations. The two varied in required storage requirements significantly, and were compared against a third estimate prepared by the project team. This baseline estimate was prepared based on the following:

The methodology is based on a 12-character schema in both compressed and uncompressed forms. For purposes of evaluation below, the estimates of data sizes using uncompressed data were used.

- Estimated mark size in packets for the EU for 2013 was 33 billion retail units. This includes both total packet production EU wide and imports (estimated 800 million units) and exports (estimated 4.3 billion units). It was assumed that this volume would remain static over the next 7 years.

- Total required data storage requirements per annum at the unit level using the 12 characters DCTA tracking schema, extrapolated for the EU resulted in 2.21 terabytes per annum or 15.4 terabytes over 7 years¹²¹.
- The project prepared a similar estimate, also using a 12 character unique identifier, and making allowance for additional data elements (including commercial traceability events)¹²², and the estimated data storage requirements for the EU market size was 2.86 terabytes per annum or approximately 20 terabytes over 7 years. A summary of this calculation is included below, illustrating the calculated data size for a single production line, that is then extrapolated for the estimated EU Market size¹²³.

¹²¹ Industry provided estimate of one 50 carton, 500 packs shipping case, recording unique identifiers of packs together with aggregation events to carton and mastercase to have an uncompressed data size of 17.40KiB. Data modelling extended this further consider aggregation event to pallet level, 8 distribution chain events, each with an estimated aggregation / disaggregation record equivalent to the full consignment, as well as an additional estimate of 40% of tobacco units being disaggregated to unit level for the final distribution event (to consider distribution for vending machine operators and mobile sales force (See 11.4.2.2.4 modelling assumptions below)

¹²²Base EPCIS message data elements were used that included production location (GLN), Date, Time (hours, minutes, seconds, milliseconds), Timezone offset, Product GTIN, 12 character unique identifier, Machine identifier, Shipping to address information, Transporter Details and Commercial document reference numbers.

¹²³ Assumption that all traceability event data is new events (i.e. no updates to existing records, instead each and every observation of an item(s) is/are stored as new entry to provide a full system audit record of all recorded events), and stored in a relational table. Commissioning events are not recorded, instead unique identifiers of packs / units are recorded during first aggregation event, at which time date and place of manufacture, the manufacturing facility, machine used to manufacture the tobacco products, product GTIN, intended market for sale and intended destination are recorded. Project calculated estimate of that one 50 carton, 500 pack shipping case recording of unique identifiers with packs, with aggregation to carton and mastercase would have an uncompressed data size of 25.38KiB.. This is modelled assuming each pack contains a unique serial number of 12 characters together with a GTIN per item giving a total of 20 characters for the unique identifier per pack . The model then extended this further to consider aggregation to pallet level, 8 distribution events per consignment with an average of 5 mastercases per consignment, each with a data size of 0.82Kb (including reference to commercial records, shipment address and transport identity and address). Further estimate that disaggregation of 40% of all tobacco products will be beyond mastercase to unit level for the final distribution event (to consider distribution for vending machine operators and mobile sales force (See 11.4.2.2.4 modelling assumptions below)

One Production Line		Number of cases	Estimated Size (KiB)
One 50 carton, 500 packs Shipping Case		1	24.11
1 hour production 500 packs / minute		60	1,446.56
24 Hours production		1,440	34,717.50
Minus stoppages (15%)		1,224	29,509.88
1 months production (20 working days)		24,480	590,197.50
Proposed Extensions			
Aggregation to a Pallet (50 mastercases per pallet)		24,480	11,803.95
Distribution Chain Links (assume 4 hops + 4 commerc		24,480	32,168.25
Disaggregation to Pack level (estimated at 40%)		9,792	236,079.00
Total		24,480	870,248.70
Average size per Unit			
Packs			0.0711
Cartons			0.7110
Mastercases			35.5494
Projected data sizes for the EU Market			
		Packs	KiB
Market Size	Domestic Consumption	28,000,000,000	1,990,765,000
	Est. Export (EUR1.4 bn)	4,361,370,717	310,088,006
	Est. Imports (EUR 250m)	806,451,613	57,337,702
Total:		33,167,822,329	2,358,190,708
Data Size (/annum)		TiB	2.20
Data Size (/annum + 30% Overhead)		TiB	2.86
Data Size (7 Years)		TiB	19.99

Table 42 - Project estimate of Data size

- This data-sizing estimate includes storage overheads for case and master cases tracking and an average of four distribution events and four commercial events. A further 30% overhead was added to account for additional database keys and indexes.
- The data modelling assumes related that references to commercial document identifiers (invoice numbers, order numbers and payment records) are stored for each traceability event, and not the commercial documents themselves, as per method 1 considered in 8.6.9 above.
- A data size of 2.21 and 2.94 terabytes per annum is not a relatively large quantity of information to be stored or transmitted, compressed or uncompressed.

Modern on-line storage systems of this size may easily be remitted to and managed from, a single source. It is anticipated that a compressed format could reduce this data size significantly, confirmed by both manufacturing data sources, where compression was shown to reduce the size by over two thirds.

Should the schema be expanded to 16 bits to include a two digit alpha-numeric code to identify the serialisation scheme, and a potential second two digit alpha code for each EU country, then the entire data set could still be easily stored, remitted to and processed at a single site, while allowing easy segregation of data from industry, and if required, from different governments or parts of government. These additional prefixes would potentially allow the case for multiple solution providers (with different code generation schemes) to generate codes with the assurances of not creating duplicates.

If the schema were expanded to a 16 bit alphanumeric schema, then uncompressed storage requirements (including 30% overhead contingency) grow to an estimated 2.45 terabytes per annum and 17.15 terabytes over 7 years.

For further improvement in data processing times, a typical production database of this size would hold two years' worth of records in an on-line database for day to day

processing and analysis, with the balance being available by accessing another instance of the database as required.

10.1.2 COMPLIANCE COSTS OF TRACEABILITY SOLUTION

All solution options will involve a cost to the EU Member States, producers and distributors. These costs may be broken into seven types:

1. Compliance costs in both time and money of different solutions supplied to, or required from, *identical* manufactures in different countries.
2. Compliance costs in both time and money of different solutions supplied to, or required from, *different* manufactures in different countries.
3. Compliance costs in both time and money of different solutions supplied to, or required from, different manufactures in the *same* countries.
4. Compatibility of data sets provided by different solution providers, even if prescribed data formats are required.
5. Additional processing requirements and reconciliation costs to Member States, manufacturers and distributors for variant systems.
6. Aggregation costs and timeliness of information when assembling data from disparate sources, even if systems and data are directly compatible.
7. Incompatible or difficult to reconcile legal storage requirements for different EU systems, especially around data release.

Traceability options 1, 3 and 4 all utilise multiple data repositories and contain compliance costs related to the seven elements identified, while the use of the multiple storage repositories potentially creates complexity risk to data integrity as a whole.

The selection of a single data storage and processing provider (option 2) would appear to be the easiest to implement, while also being the easiest to administer and the most cost effective. For these reasons, it is proposed that, a consolidated data repository be considered across all four options.

10.1.3 PRACTICALITY OF IMPLEMENTATION WITH MULTIPLE ICT VENDORS

Apart from the compliance costs detailed in section 11 below, the management of multiple vendors and multiple bid management is seen as both a significant risk and cost factor in implementing Options 1, 3 and 4 of the traceability solutions proposed.

A single supplier of service, by contrast – as per Option 2, would require a single round of bids to be considered, allow more resources to be directed at bid quality and would help ensure uniformity of compliance uptake times between Member States, manufactures and distributors.

10.2 BID PROCESS CONSIDERATION AND AUDIT AND SERVICE REQUIREMENTS

The following section outlines several key considerations when choosing and working with a Data Management Provider.

10.2.1 SUMMARY

The audit, Key Performance Indicators (KPIs), services and service obligations below are those typically required of a Data Management Provider, service or hardware provider. If a "Fee-for-Service" model is used, then many of the obligations and operational requirements below will become the concern of the Data Management Provider and would be managed internally to the contract.

Confirmation that services and hardware are managed as recommended should be explored during any SLA, software development or hardware supply/procurement negotiations and form part of any agreement.

Europe has well developed hardware distribution, ICT and power infrastructure. Given this background, the ability of any service provider to meet the standards and KPIs below should be a requirement of any such agreement.

A number of international standards are used in the development, monitoring and maintenance of all ICT service provisions, ICT Maintenance Plans and SLA. The most widely used today in the ICT industry are the COBIT, ITIL 3 and ITIL 4 standards and thus it is recommended that COBIT, ITIL 3 or 4 be adopted as the support framework for any ICT service supply Agreement.

Although hardware maintenance and supply vendors are subject to EU warranty requirements, specific warranty and servicing obligations (for example for printers or camera systems) should still be explicitly stated in any hardware agreement or contract. It is therefore recommended that given the established market in hosting services and hardware servicing in the EU, that a "Fee-for-Service" model be used for these elements.

Under a "Fee-for-Service" Model, the servicing of hardware and the provision of ICT hosting and communications services are black box operations, where all responsibility lies with the Data Management Provider. Payment is based on metrics established by KPI measurement. Typical KPIs for these services are contained in Section 10.2.6 below.

Software Development is more complex than hosting or hardware provision and will require expert requirements collection and analysis in consultation with the EU and tobacco manufactures and suppliers – please see 10.2.8 below for a high level review of a typical collection and amendment software process.

10.2.2 BID PROCESS CONSIDERATIONS

The following outlines a suggested set of evaluation criteria when evaluating potential ICT providers. In terms of data hosting, potential candidates should:

- a) Demonstrate experience providing dedicated hosting of services of a similar size and complexity.
- b) Have a publicly available security and services set of policies consistent with EU requirements and law.
- c) Be a registered member of an accepted Digital Certificate register.
- d) Demonstrate a current and secure VPN operating model EU wide.
- e) Supply a current Business Continuity Plan as part of their bid, including reciprocal hosting agreements with other vendors or be in possession of an alternate processing centre.
- f) Supply copies of their current telecommunications arrangement with telecommunications suppliers, including provisions to deal with loss of services.

- g) Accept penetration and security testing of their systems by an accepted security systems test provider as part of the bid process.
- h) Agree that hosting, including alternate or emergency hosting, is held within the EU's physical boundaries.
- i) Be subject to EU law.

Further considerations for potential candidates providing application development services (which may be needed to build or at least assist in building web-services and potentially business logic on top of the data storage for the traceability solution) should include:

- a) Evidence of previous projects developing solutions in the traceability / supply chain management domain
- b) Demonstrated experience developing applications of similar scale, and complexity.
- c) Examples of timeframes any previous projects were delivered under
- d) Competencies in the areas of business requirements analysis, system architecture design, development and software quality assurance and testing
- e) Skill set of the organisation in terms of architectures and programming languages (to validate that these are easily supportable standards and languages)
- f) Geographical location where development (and associated business analysis and system analysis activities) will take place
- g) As far as possible, create a competitive bidding process that includes cost factors
- h) Testimonials showing experience developing business applications and providing support and maintenance services
- i) Be subject to EU law.

10.2.3 USE OF CLOUD SOLUTION FOR HOSTING

In terms of the possibility of using cloud storage solutions, TPD Article 15(8) requires that the data storage needs to be available for audits, which may include physical audits of the data storage facility. Given this consideration, dedicated hosting may be a more appropriate form of providing the data storage than a cloud hosting service where a specific physical location is unspecified. This does not exclude that possibility of a cloud-like architecture being used for the hosting of data, but would apply some constraints and require the use of pre-defined servers, preferably in a limited number of physical locations, and the servers should be dedicated to the single task of providing storage, and where applicable, associated services for the traceability solution.

This last rationale was adopted by the contracting team so as to estimate costs for data storage, included under Section 11.4.2.

10.2.4 SCOPE OF SLA AGREEMENTS FOR SOFTWARE AND HARDWARE VENDORS

It is proposed that agreement entered into between the parties should contain the following audit metrics/KPIs and minimum condition and terms:

The agreement should cover:

- All processes, software, hardware, infrastructure and personnel relevant to the processing of data on behalf of the EC and using the software and/or systems and/or hardware procured or supplied under agreement.
- These elements are typically categorised into warranties and servicing of hardware, software development and servicing, and hosting and telecommunications contracts.

10.2.5 TERMS AND DEFINITIONS USED IN TYPICAL SLA SUPPORT CONTRACTS

- BCC: Business Continuity Co-ordinator
- BCP: Business Continuity Plan
- BIA: Business Impact Analysis
- DRP: Disaster Recovery Plan
- MP: Maintenance Plan (ICT Plan to Maintain a system)
- RPO: Recovery Point Objective How much Data the organisation is prepared to lose
- RTO: Recovery Time Objective Timeframe within which processing must be restored
- WP: Warranty Period (Hardware - In this instance data, bar or optical readers.)
- SF: Service Frequency (Hardware - In this instance data, bar or optical readers.)

10.2.6 GENERAL REQUIREMENTS FOR SOFTWARE/HARDWARE/HOSTING SERVICES

It is recommended that all service and hosting contracts in relation to the tobacco traceability solution should have the following minimum clauses and standards:

- Agreed security and confidentiality arrangements based on EC and EU requirements and standards. These clauses must also protect the rights and obligations of the data management providers, including the right not to have their product data and volumes exposed to their competitors or other industries or individuals. This should include physical operational measures to secure data, such as requirements for any data on any part of the system must be cleansed or sanitized under an agreed methodology prior to disposal, re-purposing or decommissioning.
- Agreed data ownership and data distribution rules covering all data, systems, methodologies, hardware and property. These clauses should also cover disclosure or non-disclosure to law enforcement and other civil authorities within the EU, as well as consider the effects and risks of hosting data outside the EU.
- Agreed data and hardware disposal and retention rules covering all data, systems, methodologies, hardware properties and property.
- Definitions of exactly what will be delivered, both in terms of hardware and software, and in what formats. Delivery includes:
 - a. Periodic hardware servicing times and servicing schedules (for example if optical reading systems or barcode printing are selected).
 - b. Warranty renewal obligations and costs.
 - c. Data definitions and standards to be used, including encryption and non-tamper standards.

- d. Definitions of the price, volume and response times of ICT hosting and software service delivery, and SF and WP response times for hardware.
- An agreed method of:
 - a. Recording service characteristics.
 - b. Measuring performance.
- Resolving disagreements, including an issues escalation and arbitration path and under what legal systems and rules.
- Terminating agreements.
- Frequency of payment.
- An agreed transition plan and duration if a decision is made to move to an alternate service provider or to terminate the agreement. This agreement/clause should clearly state the obligations of both parties during transition and handover, including handover formats and security controls and protocols and data destruction and confidentiality.
- Agreement that all password and / or system access rules are authorised, known and are available to necessary stakeholders. Access to the facility and data should account of the audit and monitoring function to be performed by external auditor [TPD Article 15 (8)].
- Agreement that all staff working with contracted software, hardware or systems is formally qualified in the speciality that they are addressing. Examples include:
 - a. Oracle/SQL/Database contract staff must be Oracle/SQL/Database certified.
 - b. Server Maintenance and other staff are qualified in servicing the models and types of equipment they are working on.
 - c. Certifications must remain valid.
 - d. Certifications must include a specific acknowledged IT Management methodology, for example ISO9000 family of standards, ITIL or COBIT.
 - e. Recognised certificate or qualification to service and/or install Hardware.
- Agreement that:
 - a. Qualifications claimed by service or hardware providers, their employees or agents must be able to be verified by the party engaging the data management provider's services.
 - b. Any services provided or contracts or agreements entered in cannot be assigned to another party without the prior, written consent of the party engaging the data management provider's services.
 - c. Performance demonstrations of competency or operability, and performance testing where necessary, may be requested by the EC according to a frequency and in a fashion requested by the EC for the purposes of the EC to assess the suitability of the Data Management Provider.
- For software provision or software hosting:
 - a. An initial BIA addressing risks internal to the service provider and external to party engaging the data management provider's services, as a potential consideration by the EC in assessing the suitability of a Data Management Provider.
 - b. Further, this may include a BCP Plan, addressing all risks identified in the BIA

- c. An agreed DRP Plan, addressing all risks identified in the BIA, must be available on demand to the EC and submitted for approval prior to final acceptance of the initial Agreement or Contract.
 - d. Agreement that the BIA, DRP and BCP will be updated as required and reviewed and re-submitted at least annually.
- Clauses covering partial removal or deferral of services.
 - Clauses covering the provision of additional services or volumes.
 - Agreed renegotiation dates and times, including renewal timings.
 - List of Technical documents covering hardware, including warranty registration.
 - Appendices covering agreed software functionality requirements.
 - Clauses covering delays in implementation and or delivery – supplier.
 - Delays in implementation and or delivery - client.
 - Delays caused by third parties engaged by either party or by an unrelated party.
 - No harmful code requirement. This does include embedded hardware control logic, not simply software.
 - Insurance and liability requirements and obligations by all parties.
 - Escrow arrangements for both hardware and software suppliers and software developers.
 - Requirement for software suppliers to develop all code under legitimate licensing schemes.
 - Software licencing terms and conditions to the EC and/or other parties, including software renewals and transfers to third parties.
 - Clauses covering software and hardware upgrades – mandatory or voluntary – that stakeholders interacting with the Data Management Providers may become subject to by the use of acceptance of any software, hardware and/or other service provided by a vendor.
 - Requirement to act transparently and ethically as per EU and EC requirements.

10.2.7 SPECIFIC SERVICE REQUIREMENTS FOR ICT HOSTING PROVIDERS

- Service provision should be via clustered physical and virtual servers. This support architecture ensures that, should a server fail, the service being provided continues automatically.
- Service provision should always include processing capability at an alternate site to maintain continuity of service, should the original host site fail.
- The alternate processing centre should have all the capabilities of, and be of identical configuration to the primary site, including security.
- Given the quality of European infrastructure, a RPO - Recovery Point Objective - of zero loss of data should be an expected KPI.
- Given the quality of European infrastructure, a RTO - Recovery Time Objective - of zero loss of time should be an expected KPI.
- Access to agreed, accepted, deployed and tested software, should be available at agreed locations 24 hours per day, seven days of the week.
- Full password security on all hardware and software systems.
- The use of a virtual private network for all network communications and linkages, internal and external.

- That HTTPS, (not http) be a minimum standard and the basis for all Internal and external web- based traffic.
- An agreed encryption protocol for all data communications using an accepted public key encryption system.

10.2.8 ADDITIONAL GENERAL SERVICE REQUIREMENTS FOR HOST PROVIDERS

In addition to the specific and general service provider requirements listed above, there are several requirements that should be confirmed with the service provider in whole or part. However, these do not necessarily affect the development of technical standards for the traceability solution, and have therefore not been included here, but can be reference in Annexure 9 below for further consideration.

10.3 BACKUP SERVICES

The crux of ICT SLAs is continuity of quality, secure, service and the ability to restore systems in an agreed and timely fashion. For this to occur an appropriate backup strategy is required. Within the EU, its proposed that as a minimum, the following staged backup system should be part of any SLA:

- Clustered servers for business continuity.
- Daily incremental on site.
- Daily full at COB each day and stored offsite.
- Weekly full and stored offsite.
- Live to the alternate processing centre.

Backups should consist of server and software configuration parameters as well as the production database and software.

The following backup tasks are normal KPI and SLA requirements for any ICT contract:

- Verify previous days live backups each morning.
- Verify previous days live backups each morning at alternate processing centre.
- KPI: Verification check records are entered each day in the operations register.
- KPIs shall be available by electronic report on demand from the help desk.

10.4 RESTORATION SERVICES

Equally important to backing up, is the ability to restore lost data in the event of failure. Regular practice of this task must be part of any SLA.

- Restore to test server from backup server to ensure server backups are working.
- KPI: Verification check records entered each day in operations register.
- KPIs shall be available by electronic report on demand from the help desk.
- Restore to Test Server from last backup to ensure backups are still working.
- Restore to Test server from alternate processing centre.

11 COST / BENEFIT ANALYSIS

In accordance with the objective of the contract, as mentioned under 3.2 of the tender specifications, CHAFEA and the Commission should be provided with:

- A cost / benefit analysis of the four possible alternative options for traceability solutions for tobacco products assessed. This analysis aims to understand the impact of such solutions on manufacturers, distribution chain operators (differentiating between large enterprises and SMEs when possible) and Member State authorities.
- A cost / benefit analysis for the four alternative options for security features in the European Union, for the economic operators involved.

This section will provide CHAFEA and the Commission with a cost/benefit analysis that will first provide the rationale used in deriving all figures; followed by a summary of the results for the four traceability options and four security feature options, a description of the rationale and assumptions of the cost/benefit analysis itself; and finally, a detailed walkthrough of each of the solutions (both track and trace and security features), to include evaluation criteria/sub-criteria and methodological approaches.

The cost/benefit analysis is a modelling exercise to estimate what the costs would be using limited inputs, whilst benefits are modelled using techniques used in previous academic, European Commission, WHO and industry reports. There is always an inherent challenge measuring benefits related to illicit trade – by its very nature it attempts to be “invisible”, and estimates of its magnitude need to be treated with caution where they may be ulterior motives to overstate or understate.

In addition, while we have attempted to estimate the costs using information that has been shared during the study, we have to be mindful that these are private organisations (competitors), and that the true cost would only be established through a competitive tender process. It is not the intention of this report to establish these actual commercial amounts, but rather the indicative amounts.

This analysis was based on a series of publicly available reports and studies relative to illicit trade and the responses from a survey prepared and distributed to relevant stakeholders in the field, including Member States, traceability and security feature solution providers, industry associations/professional bodies and the tobacco manufacturers. Some assumptions were made during the analysis to compensate for the fact that a lower level of survey response was received, than expected. These quantitative assumptions are clearly outlined below in the analysis, as they may have some impact on the final analysis. However, it should be noted that the quantitative model was built in such a way that it is easy to change quantitative assumptions (or variables), if desired, and the final results are adjusted automatically.

11.1 TRACEABILITY SOLUTION OPTIONS: COST/BENEFIT ANALYSIS

A cost benefit analysis was completed for each of the four traceability solution options. This analysis endeavours to provide CHAFEA and the Commission a clear idea of cost advantages and disadvantages for each solution. The cost impacts were calculated at a

combined European Union / Member State level. The assessment considered both qualitative and quantitative benefits, applying the EU impact assessment guidelines¹²⁴.

In addition to the data collected from the survey completed by stakeholders (including solution providers, Member States, associations, professional bodies and tobacco manufacturers), publicly available reports and studies were also used to compile this analysis.

11.1.1 ASSESSING SOLUTION COSTS

Although it is currently unclear to what extent individual Member States will implement additional capacity to oversee a tobacco traceability solution, and business requirements for each Member State have not yet been determined, the analysis does include estimations for both of these components given their importance as considerations that affect the final analysis. It should be noted that these estimations can be refined as Member States develop their business requirements.

The solution costs for Member States include:

- The additional labour force requirements to conduct audits, inspections and enforcement activities. (It should be noted that the traceability system can provide potential savings in other aspects of the national administrations, for example, for Customs Authorities – a full analysis of these savings would require further research outside of the parameters of this report.)
- The development and maintenance of an information system to administer the proposed traceability solution.

When assessing the impact of the traceability solution on manufacturers and distribution chain operators, the following costs were included:

- Installation of marking / label applicator equipment on production lines,
- Independent line monitoring equipment,
- Monitoring / scanning equipment required for data aggregation,
- Estimated cost for system development effort for manufacturers to provide information required for aggregation (packs, cartons, master cases and pallets), and
- Cost for compliance monitoring activities.

Assessing the above costs included both fixed and operating costs for implementation and operation of the solution:

- Investment costs (CAPEX, or capital expenses) associated with implementation of equipment at manufacturing sites, production lines and within the distribution chain. Also included was the required technical infrastructure for data exchange and implementation of the required data storage (repository).
- Operating costs (OPEX, or operating expenses) associated with marking items, packaging materials and associated per-unit costs incurred for process and business activities required to enable the traceability solution. Further, operating costs associated with the information technology infrastructure.

¹²⁴ http://ec.europa.eu/governance/impact/commission_guidelines/docs/iag_2009_en.pdf

11.1.2 ASSESSING SOLUTION BENEFITS

Solution benefits were analysed using two quantitative factors that considered:

- **Public health savings:** by reducing the supply of under-priced illicit cigarettes, using price elasticity estimates, a reduction in smokers is expected. In addition, academic literature proposes a corresponding decrease of expected Non Communicable Diseases (NCD), with an associated reduction in the NCD economic burden for the 28 Member States. Projected public health savings will be calculated for each Member State.
- **Increased fiscal revenues:** for each % of the current tobacco market that is illicit, a potential tax loss amount can be calculated. Again, depending on price elasticity figures available, tax benefits of implementing a traceability solution can be estimated, given distinct levels of impact – low, medium or high - that such solution could have on illicit trade.

From a qualitative perspective, improving the functioning of the internal market and combatting illicit aids the objectives of the TPD. A decrease in an overall reduction of tobacco consumption could in turn result in consumers smoking less or quitting smoking altogether. If there is a reduction in consumption this could mean less absenteeism from work on a daily basis and possibly a decrease in the number of people retiring early, due to smoking-related health issues. Furthermore, a reduction in smoking will impact the life expectancies of these smokers, thus prolonging their lives to the levels of non-smokers. Other benefits may include increasing the effectiveness of national tax and health policies, which include curbing tobacco demand and meeting supply objectives, promoting consumer protection and health improvements, fighting illicit trade and criminal organisations and supporting fair economic practices for legitimate tobacco companies and distributors.

11.2 SECURITY FEATURES OPTIONS: COST / BENEFIT ANALYSIS

A cost/benefit analysis was also completed for each of the four security features solutions. This analysis should give CHAFEA and the Commission a clear picture of the cost advantages and disadvantages for each solution and provide information to enable them to make a decision as to which solution best meets EU requirements and needs.

The cost assessment for security features considered three components:

- Implementation costs associated with production equipment and infrastructure required to apply the security features to products, and
- Operating costs associated with production/application of security feature applied to each product.
- Operating costs associated with devices/equipment required to validate the security features on products.

11.3 SUMMARY OF FINDINGS

A comprehensive traceability solution will provide traceability and control of the distribution chain and will contribute to the functioning of the internal market by establishing a control infrastructure for legitimate tobacco products. At the same time, it will aid in reducing the illicit supply of tobacco by increasing its potential detection which will support European law enforcement and public health entities engaged in combatting illicit trade. Illicit trade in tobacco products undermines *inter alia* the safeguards of the TPDs. Adding special security features at the EU level will help to further reduce sales of

these products and further facilitate the functioning of the internal market of legal tobacco products.

The costs associated with these measures are outweighed by the benefits in terms of reduced illicit trade, which ultimately benefits legitimate manufacturers and supply chain actors.

Note: Tobacco products other than cigarettes and RYO tobacco will have an additional 5-year period to fulfil the obligations laid down in the TPD (Article 15 and 16) regarding Traceability and Security Features. The producers of OTP may benefit from the extended deadline, as they can learn from previous experience and identify system requirements that would help reduce investment needs.

11.3.1 BENEFIT ANALYSIS

The four solution options for both traceability and security features are designed to address most of the issues identified in the problem statement. While the costs associated with these different options may differ, the benefits are related to the solution objectives that are similar across all the options. As there is no effective way to differentiate the quantitative benefits for these individually, this study analysed their impact from a holistic point of view, assuming that any option selected would achieve similar objectives, and to some degree, reduce the number of illicit and non-conformant tobacco products on the EU market. All other benefits considered were estimated as a result of this reduction.

Despite the fact there is no effective way to differentiate the benefits from one option to another, the key success factors and advantages/disadvantages of each option can influence the likelihood of realizing those benefits to a variable extent. Therefore, one should avoid concluding that the solution to be chosen will simply be the cheapest one where a potentially lower degree of benefits realization could negatively compensate apparent savings in costs.

Current studies state that illicit trade of tobacco is between 8% and 12% of the total EU market. The Team used the figure of 8.25% in conducting its analysis, with the assumption of 30% being contraband, 50% being counterfeit and 20% being illicit whites.

Furthermore, for the purposes of modelling the benefits, the project team used the assumption based on previous studies experiences that indicates implementing a traceability policy combined with security features could lead to a reduction of illicit tobacco products available on the market. These studies maintain that an effective Traceability (T&T) + Security Features (S/F) policy could have the following impact on the illicit trade¹²⁵:

- 30% reduction on contraband
- 10% reduction on counterfeit
- 10% reduction on illicit whites

¹²⁵ The input values for the analysis are based on the European Commission's Impact Assessment for a Tobacco Product's Directive (see: SWD (2012) 452 final). However, given the fluctuation of the illicit tobacco trade and the inherent problems of measurement, the exact values may differ. Therefore, the Project Team has carried out an alternative calculation on the basis of a changed, but also plausible set of assumptions (see Figure 15). The alternative calculation provides for the range of results consistent with the present calculation, i.e. the expected benefit indicated in Figure 14 falls within the range indicated in Figure 15.

Applying these potential illicit trade reductions in the context of the estimates of contraband, counterfeit and illicit white estimates in the EU and calculating the impact shows a impact equivalent to 1.32% of the EU total market as a consequence of the T&T + S/F policies implementation. This calculation is illustrated in Figure 49 below:

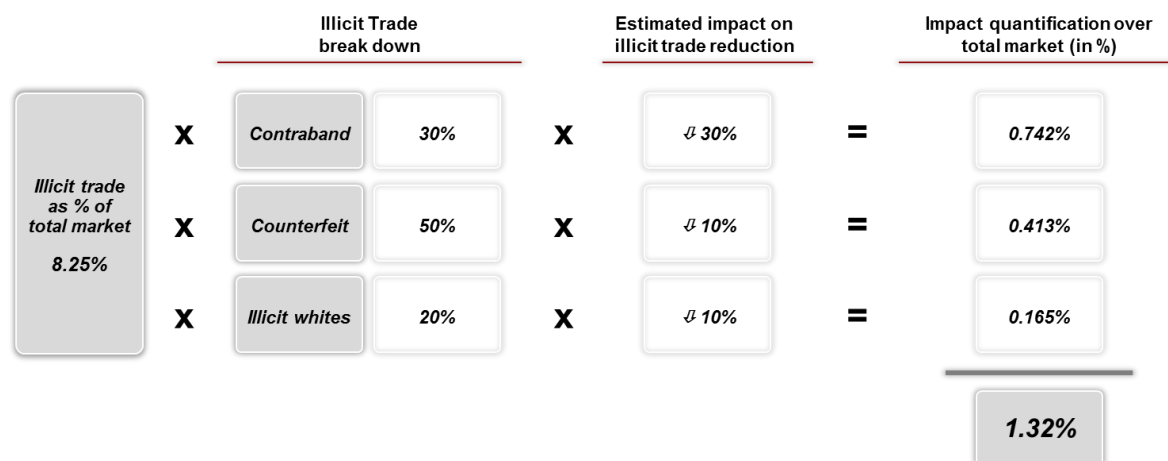


Figure 51– Impact on illicit trade calculation and quantification vs. total market

If estimating that total EU consumption is equal to 559 Bn sticks (27 950 M packs, considering an average of 20 sticks per pack), 1.32% of the total EU market is equal to approximately 368.9 M packs.

It is assumed that this reduction comes directly from the illicit market (legal tobacco sales should not be directly affected by the implementation of traceability and security feature policies), and translating this theoretical reduction to the impact on the consumer, a price elasticity of tobacco demand in the high-income segment was assumed to be ~-0.4, (studies maintain that it lies between -0.2 and -0.8 in low and middle income countries¹²⁶). In determining the effect of price elasticity the team estimated the average price of the illicit product is approximately 50% that of the average price on the EU legal market, accounting for a proportion / full amount of excise taxes that are evaded on illicit products.

This elasticity effect means that, as described in the European Commission impact assessment of December 2012, a portion of the consumer demand will return to the legal supply chain paying the high price of the legitimate tobacco product, whilst the other portion of consumers will not start smoking, stop smoking or smoke less. Also, consumers are better informed on health risks of tobacco products that fully abide to the TPD requirements.

The existing data also allows for initial quantification of the proposed system's expected effects on the quantities supplied by the licit manufactures. After excluding the contraband, the demand for the licit products can be expected to increase by 0.35%, which equals to the sum of 0.413% (the impact on counterfeit) and 0.165% (the impact on illicit whites) multiplied by 0.6 (the diversion ratio). However, given the conservative nature of the present cost-benefit analysis, the benefits for the licit manufactures are not taken into account in the overall calculation of benefits stemming from the introduction of the proposed system

¹²⁶ European Commission – Impact Assessment for a Directive of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products.

Using the price elasticity estimate above, it is therefore estimated that the reduction of the illicit market will result in a change in demand consumption where 60% of the people who buy illicit cigarettes today will start purchasing legitimate products, and 40% will be a reduction, where smokers either quit or reduce smoking. Considering this, we can split the T&T + S/F implementation impacts into two separate effects, translated into volumes of tobacco units:

- 60% of people will go 'legal', meaning 221.4 M more packs will be purchased legally (0.79% of total consumption)
- 40% of people will quit or reduce smoking, meaning 147.6 M packs will not be sold on the illicit market (0.53% of total consumption)

Each of these numbers will affect different drivers. While the number of people that will reduce or quit smoking will have an impact on public health and social indicators, the people that go 'legal' will impact the amount of new taxes and public revenue collected, as shown below.

- Tax revenues from legal tobacco will increase to € 736 m per year.
 - Related to VAT, € 169 m per year
 - Related to excise duties and similar charges other than VAT, € 567 m per year

In addition to these economic impacts, recent studies prove that when there is a reduction in tobacco consumption, there is also an overall improvement to public health and related costs as non-smokers live longer and benefit from healthier lives¹²⁷. Based on this, the project team calculated the following impacts related to public health (benefits associated with people quitting / reducing tobacco consumption):

- 0.6 m smokers will stop smoking.
- Reduction of annual health care expenditure of € 134 m.
- Reduction of related societal losses of € 44 m, due to:
 - Reduction in smoking induced early retirements (€ 32 m)
 - Reduction in smoking-induced absenteeism (€ 12 m)

Additionally, it has been estimated that smokers who die as a result of their tobacco consumption, die 14 years earlier than people who never-smoked. Further, increased awareness of dangers of tobacco is anticipated to lead to a change in behaviour.

The following Figure 50 outlines the impacts discussed above:

¹²⁷ European Commission – Impact Assessment for a Directive of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products

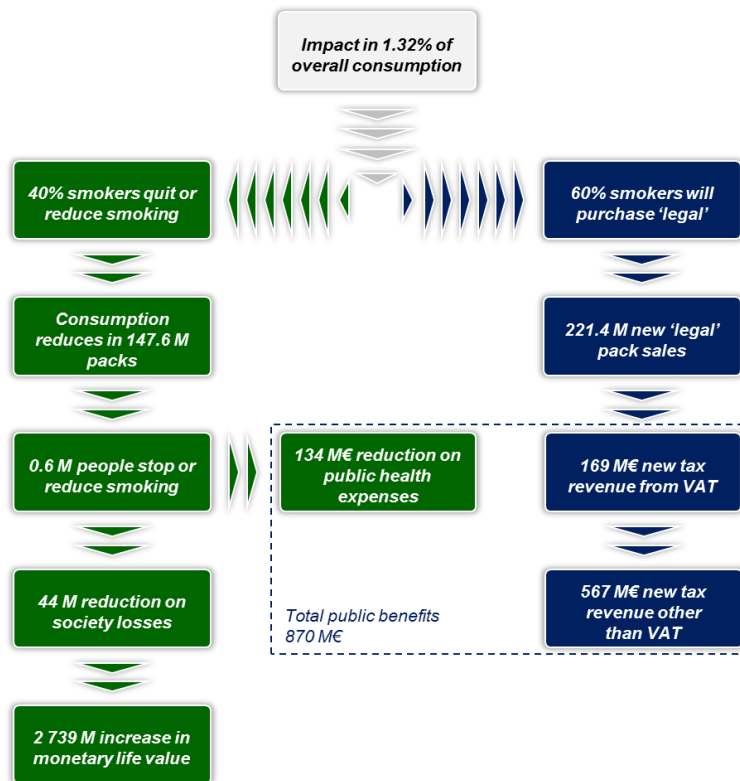


Figure 52– Benefit Analysis I: Key Figures

Recognizing that publicly available studies, like the ones we have used and were referred to in Figure 50, including the European Commission’s Impact Assessment for a Tobacco Product Directive [see: SWD (2012) final], are two or three years old, and that changes could have occurred in the size of the illicit market, as well as on the breakdown of illicit trade (and the estimated impact of T&T+S/F solutions themselves on such trade), the project team attempted to look for additional insight from other industries, specifically the pharmaceutical industry to estimate figures for benefits from implementing a T&T+S/F solution. Unfortunately, despite extensive research, no reports were found. The project team then looked at other sources, such as Euromonitor, a research group that studies the tobacco and alcohol market around the world. Euromonitor stated that in 2012 the illicit tobacco market in the EU is 10% of the total market. In 2013, because of a significant increase in Spain, the number was 12.5%. Euromonitor does not, however, break down its data to show the % of counterfeit, contraband vs. cheap whites.

Using the 10% as a reference figure, the project team prepared a sensitivity analysis, where three scenarios were analysed: a 10% impact on illicit trade would mean a “low” outcome, 20% would correspond to a “medium” outcome and 30% to a “high” one.

The following calculations provide for a range of plausible values in terms of expected public benefit (see Figure 51 below).

Illicit trade as % of the total market (in %) = 10%			
	Low impact scenario	Medium impact scenario	High impact scenario
Estimated impact on illicit trade reduction (in %)	10%	20%	30%
Impact quantification on total market consumption (in %)	1.00%	2.00%	3.00%
Impact quantification on total market consumption (in M packs)	279	558	838
40% smokers quit or reduce smoking			
Consumption reduction (in M packs)	112	223	335
Number of people quitting smoking (in M people)	0.5	1.0	1.4
Increase in society productivity (in M euros)	33	66	99
Reduction on public health expenses (in M euros) A	101	202	304
60% smokers will 'go legal'			
New legal sales (in M packs)	168	335	503
New tax revenues from VAT (in M euros) B	128	256	384
New tax revenues other than VAT (in M euros) C	429	857	1 287
Total Public benefits (in M euros) A + B + C	658	1 317	1 975

Figure 53– Benefit Analysis II: Key Figures

In conclusion, estimates for total public benefits range from a minimum of € 658 m to a maximum € 1 975 m, in all cases outweighing total estimated costs as described in the next section of this report.

11.3.2 COST ANALYSIS

The cost analysis was done separately for each of the four traceability solutions and security features options, taking into consideration three key stakeholders: Member State authorities, tobacco manufacturers and distribution chain operators (including wholesalers and other agents / distributors comprised of Vending Machines Service Companies and Mobile Sales Force Companies¹²⁸). The diagram below (Figure 52) displays the scope of the analysis for this report:

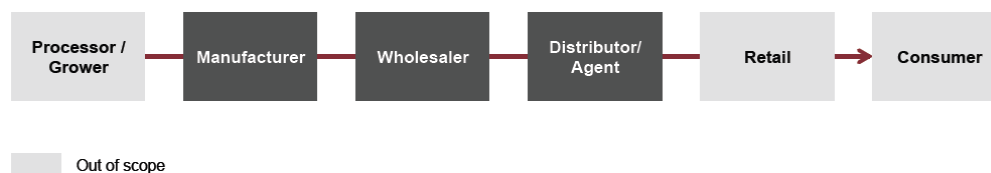


Figure 54– Scope within the Context of the Tobacco Supply, Manufacture and Distribution Chain

¹²⁸ European Commission – Impact Assessment for a Directive of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products

As a starting point, while we have attempted to estimate the costs using information received from the surveys sent to stakeholders, the project team was mindful that these are private companies (competitors), and that the true cost would only be established through a competitive tender process. It is not the intention of this report to establish these actual commercial amounts, but rather the indicative amounts.

For manufacturers, the analysis considered three different types of costs:

- One-off capital expenditures and costs (CAPEX)
- On-going costs (OPEX)
- Other additional costs (as the costing methodology explains in further detail, the proposed approach advocated obtaining cost estimates from existing implementations as a base for Option 1, and then rationalising the variations to this for the subsequent options; these variations were included here).

As seen in Figure 53 below (see also comments in section 11.4), the cost differences with regard to Options 1-3 are negligible, with Option 4 being estimated as the lowest cost option. Option 4 seems cheaper in terms of traceability but one must take into consideration that some costs are integrated in the security features cost analysis. This means that for Option 4, the traceability component and security feature component needs to be considered together, rather than in isolation.

	T&T Option 1	T&T Option 2	T&T Option 3	T&T Option 4
CAPEX	122.1 M€	122.1 M€	122.1 M€	77.0 M€
Annual depreciation	20.3 M€	20.3 M€	20.3 M€	12.8 M€
OPEX	66.2 M€	66.2 M€	66.2 M€	0.6 M€
Additional costs (OPEX)	-	8.7 M€	22.5 M€	-
Annualized total costs (OPEX + annual depreciation)	86.5 M€	95.2 M€	109.0 M€	13.4 M€
Average € / unit ⁽¹⁾	0.0026 €	0.0029 €	0.0033 €	0.0004 €

(1) Calculated over 'Annualized total costs' - Considering 33,014 M units in the EU (28,000 M cigarette packs + 2,800 M cigarette cartons + 959 M units cigars + 1,013 M units RYO + 80 M packs pipe tobacco + 1.8 M packs chewing tobacco + 160 M packs snus)

Figure 55– Traceability Cost Analysis for Manufacturers

It is important to highlight that there are differences between stakeholders within the cost model scope in terms of expected cost implications of implementing a traceability solution. As a result of the tobacco anti-smuggling agreements signed between certain manufacturers and the EU and certain Member States⁸, several large tobacco manufacturers have already started implementing traceability solutions within their respective supply chains. The tobacco industry’s solution (as proposed by DCTA including the Codentify code assignment module), has been used as the basis for each of these and has commenced implementation at Philip Morris, Japan Tobacco International, Imperial Tobacco and British American Tobacco.

One of the largest companies is expected to have Codentify fully operational (pack and carton level coding, supply chain traceability) by December 2014 (excluding other tobacco products). Our cost benefit analysis has taken these survey responses into

consideration, however, since each of the companies have undertaken the initiative on their own, with their own chosen systems integration vendors and technology choices, (e.g. ERP software integration, cameras, printers, etc.) we have had to develop a customized approach. This is to ensure an “apples-to-apples” analysis that is based on a common set of assumptions and data inputs, so the degree of implementation of each participant of the survey was not considered.

The cigar market, which accounts for 2.9% of the total tobacco market, was also considered in the cost analysis. Estimates obtained an association of cigar manufacturers in the EU indicated some 550 finishing stations (cigar production areas where products are prepared for the intended market of sale) would potentially be impacted. In assessing the potential impact of the four proposed solutions on these stations in EU, two different costs have been considered:

- Utrack kit (CAPEX)¹²⁹
- Packaging and labelling costs (OPEX)

As seen in Figure 54 below, the cost of Option 4 in terms of traceability is the lowest – however it is important to consider that additional costs are integrated in the security feature for this option (given that aspects of the traceability solution is integrated with the security feature). Therefore for Option 4, the traceability component and security feature component needs to be considered together, rather than separately.

	T&T Option 1	T&T Option 2	T&T Option 3	T&T Option 4
Utrack Kit (CAPEX)	5.5 M€	5.5 M€	5.5 M€	5.5 M€
Annual depreciation	0.9 M€	0.9 M€	0.9 M€	0.9 M€
Packaging and labelling costs (OPEX)	2.4 M€	2.4 M€	2.4 M€	0.3 M€
Annualized total costs (OPEX + annual depreciation)	3.3 M€	3.3 M€	3.3 M€	1.2 M€

Figure 56– Traceability Cost Analysis for Cigar Manufacturers

The cost implications on the distribution channel are expected to be similar across the four options (given the same implications identified in the analysis in 8.1 above). There, same the cost analysis was applied to all four solution options.

The EU distribution market (without including manufacturing and retail) is composed of 2,450 wholesaler companies¹³⁰, 7,690 warehouses or distribution facilities, 1,944 vending machines service vans (VMS Vans) and 3,699 mobile sales force units (MSFUnits). Annualized total costs estimated (OPEX + depreciation) for the entire EU distribution channel amounts to € 140 m, as seen in Figure 55 below:

¹²⁹ Utrack kit (PC + 2 scanners and related software)

¹³⁰ Eurostat 2012

	Wholesalers	VMSVans	MSFUnits	Total
CAPEX	137.7 M€	21.4 M€	40.4 M€	199.5 M€
Annual depreciation	23.0 M€	3.6 M€	6.7 M€	33.2 M€
OPEX	51.9 M€	21.0 M€	34.2 M€	107.1 M€
Annualized total costs (OPEX + annual depreciation)	74.9 M€	24.6 M€	40.9 M€	140.3 M€
Average € / unit ⁽¹⁾	0.0023 €	0.0008 €	0.0012 €	0.0043 €

(1) Calculated over 'Annualized total costs' - Considering 33,014 M units in the EU (28,000 M cigarette packs + 2,800 M cigarette cartons + 959 M units cigars + 1,013 M units RYO + 80 M packs pipe tobacco + 1.8 M packs chewing tobacco + 160 M packs snus)

Figure 57– Traceability Cost Analysis for Distributors

The cost analysis of the security features was based on the cost of the proposed security feature options presented in sections 9.2 to 9.5, as follows:

- Security feature package similar to fiscal markings,
- Security feature package to complement a digital traceability solution,
- Security feature packaging using emerging covert technology, and
- Security feature package integrating the traceable unique identifier.

Cost impacts were calculated for each of the options based on the unitary range costs received from the industry surveys, summarized in Figure 56 below:

	S/F Option 1	S/F Option 2	S/F Option 3	S/F Option 4
CAPEX	-	-	33.5 M€	-
Annual depreciation	-	-	5.6 M€	-
OPEX	75.2 M€	63.9 M€	88.7 M€	141.2 M€
Annualized total costs (Annual depreciation + OPEX)	75.2 M€	63.9 M€	94.3 M€	141.2 M€
Average € / unit ⁽¹⁾	0.0023 €	0.0019 €	0.0029 €	0.0043 €

(1) Calculated over 'Annualized total costs' - Considering 33,014 M units in the EU (28,000 M cigarette packs + 2,800 M cigarette cartons + 959 M units cigars + 1,013 M units RYO + 80 M packs pipe tobacco + 1.8 M packs chewing tobacco + 160 M packs snus)

Figure 58– Security Feature Cost Analysis

The TPD outlines the tobacco traceability requirements (Article 15) and security feature requirements (Article 16). Therefore, as commented above, to identify the overall costs, the model requires that you consider the combination of the traceability cost component together with a security feature solution, taking into account the interdependency

between two in the fourth option. All valid combinations between traceability and security feature solutions are shown as decision map on the diagram below (see Figure 57):

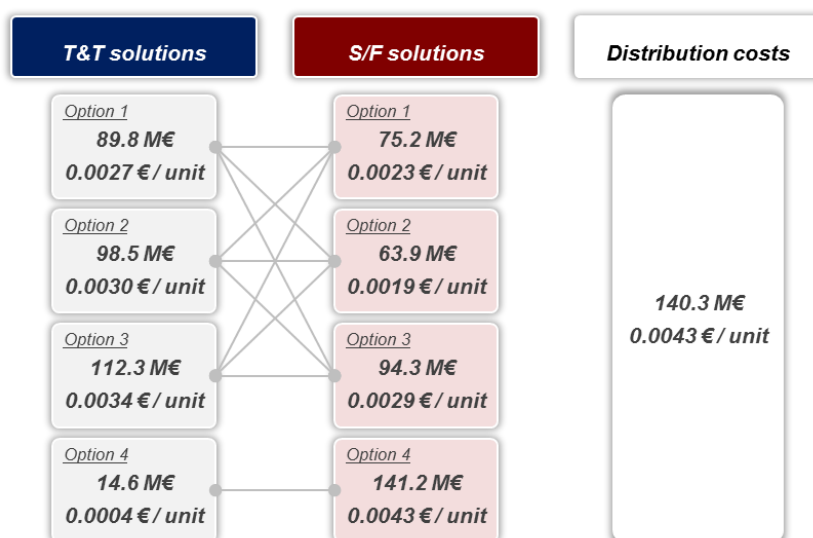


Figure 59– Traceability and Security Feature Option Possible Combinations (data included: annualized total costs – OPEX + depreciation)

The decision map allowed the project team to estimate total annualized costs (OPEX + annual depreciation) and € cost per number of items unit to be marked for the possible combinations of traceability and security feature options.

Total annualized cost impact (OPEX + depreciation) are shown in Figure 58 below:

	S/F Option 1	S/F Option 2	S/F Option 3	S/F Option 4
T&T option 1	305.3 M€ 0.0093 €/unit	294.0 M€ 0.0089 €/unit	324.4 M€ 0.0099 €/unit	-
T&T option 2	314.0 M€ 0.0096 €/unit	302.7 M€ 0.0092 €/unit	333.1 M€ 0.0102 €/unit	-
T&T option 3	327.8 M€ 0.0100 €/unit	316.5 M€ 0.0096 €/unit	346.9 M€ 0.0106 €/unit	-
T&T option 4	-	-	-	296.1 M€ 0.0090 €/unit

Figure 60– T&T + S/F option total cost calculations (data included: annualized total costs – OPEX + depreciation)

The cost / benefit analysis shows that the combination of traceability Option 1 + security feature Option 2 solution would have the lowest cost impact on manufacturers and distribution chain operators. The total annualized costs (OPEX + annual depreciation) for this combination would add up to € 294.0 m (0.0089 euros / unit marked).

- Traceability solution annualized costs - manufacturing = € 89.8 m (0.0027 euros / unit marked)
- Security Feature solution annualized costs = € 63.9 m (0.0019 euros / unit marked)

- Traceability solution annualized costs - distribution = € 140.3 m (0.0043 euros / unit marked)

On the other hand, the least cost effective combination would be traceability Option 3 + security features Option 3. Total annualized costs (OPEX + annual depreciation) for this option would add up to € 346.9 m (0.0106 euros / unit marked).

- Traceability solution annualized costs - manufacturing = € 112.3 m (0.0034 euros / unit marked)
- Security Feature solution annualized costs = € 94.3 m (0.0029 euros / unit marked)
- Traceability solution annualized costs - distribution = € 140.3 m (0.0043 euros / unit marked)

In addition to the cost impact on manufacturers and distributors, it is important to understand the economic implications of the four proposed traceability solution options on Member States. This assessment was performed as a separate exercise and considered costs associated with the development and maintenance of an IT system to run the agreed traceability solution and the labour costs related to additional personnel to support Member State authorities' monitoring, controlling and enforcement activities.

Considering that an IT company will be responsible for the development and maintenance work of the components of the traceability system to be operated by Member States, the total cost for implementing the IT system for either one of the four traceability solution options are assessed in two different scenarios (associated with different average daily charge rates), as Figures 59 and 60 summarize:

	T&T Option 1	T&T Option 2	T&T Option 3	T&T Option 4
Development Costs (CAPEX)	1,480,500 €	850,500 €	2,047,500 €	2,047,500 €
Annual depreciation	246,750 €	141,750 €	341,250 €	341,250 €
Maintenance Costs (OPEX)	222,075 €	127,575 €	307,125 €	307,125 €
Annualized total costs (OPEX + annual depreciation)	468,825 €	269,325 €	648,375 €	648,375 €

Figure 61– IT system development costs (average daily charge rate = 700 €)

	T&T Option 1	T&T Option 2	T&T Option 3	T&T Option 4
Development Costs (CAPEX)	2,538,000 €	1,458,000 €	3,510,000 €	3,510,000 €
Annual depreciation	423,000 €	243,000 €	585,000 €	585,000 €
Maintenance Costs (OPEX)	380,700 €	218,700 €	526,500 €	526,500 €
Annualized total costs (OPEX + annual depreciation)	803,700 €	461,700 €	1,111,500 €	1,111,500 €

Figure 62– IT system development costs (average daily charge rate = 1,200 €)

In addition to the IT system related costs, Member States are expected to bear additional costs due to incremental increase in labour force within law enforcement agencies. Although it is not possible to estimate the total labour cost for EU, due to the low number of Member State survey responses, the costs were estimated and calculated (Figure 61) and suggest the economic impact of labour costs on the EU of each traceability solutions. Calculations are based on information provided by Member States regarding workforce numbers and roles, as well as tobacco movements. To calculate the impact, workforce numbers for inspection and audit roles were taken into account, as well as, when available, average wages and salaries for public administration and defence staff for the Member States, as referenced in Eurostat 2012.

	Inspection + Audit staff	T&T Option 1	T&T Option 2	T&T Option 3	T&T Option 4
MS "A"	28	75,163 €	18,791 €	37,582 €	18,791 €
MS "B"	65	162,760 €	40,690 €	81,380 €	40,690 €
MS "C"	155	492,528 €	123,132 €	246,264 €	123,132 €
MS "D"	33	314,332 €	78,583 €	157,166 €	78,583 €

Figure 63– MS incremental labour costs for inspection and audit roles

In conclusion, different approaches and combinations can be used. The cost/benefit analysis shows that no matter which traceability and security feature option is selected, the benefits clearly outweigh the costs from both economic and social perspectives.

11.4 EVALUATION CRITERIA AND SUB-CRITERIA

The current section provides CHAFEA/EU Commission with the variables used in calculating the benefits and costs associated with each of the traceability and security feature options.

11.4.1 BENEFIT ANALYSIS

The benefit analysis was based on several key figures detailed in Figure 50. There is a rationale included for each figure.

11.4.1.1 MARKET SIZE

The benefit analysis started by looking at the Legal Domestic Sales (LDS), specifically at the legal sales to other countries from the EU, and then subtracting outflows of legal sales to estimate legal domestic consumption. The total EU cigarette consumption for 2013 was 559 billion cigarettes, as estimated by an industry-sponsored report called Project Sun¹³¹. While there has been criticism of the previous Project Star report (predecessor to Project Sun), these were not related to market size estimates, which are congruent with previous estimates adjusted for the EU historical rate of decline of tobacco volumes in recent years¹³².

The figure is derived using the value of legal domestic sales, from which outflows are deduced, and to which non-domestic inflows from other countries are added in, so as to obtain an estimate for the total consumption within the EU market (covering licit and illicit inflows and outflows):

Data 2013	EU Total (in Bn sticks)
Legal Domestic Sales (LDS)	507.6
(-) Outflows	(-34.8)
(+) Inflows	86.4
Manufactured cigarette consumption	558.5

Figure 64– Manufactured cigarette consumption calculation

11.4.1.1.1 IMPACTS IN LEGAL MARKET AND OVERALL CONSUMPTION AFTER ILLICIT TRADE REDUCTION

It should be noted that any decrease of illicit trade may have two possible effects:

- It will increase tobacco sales in the legal market; and/or
- Some smokers will stop smoking / not to start smoking.

As referred to in 11.3.1, the introduction of a T&T and S/F solution could reduce the illicit market with a net effect of a 1.32% decrease. Moreover, recent studies estimate that price elasticity of tobacco demand in the high-income segment is ~ -0.4 , while it lies between -0.2 and -0.8 in low and middle-income countries¹³³. The same studies indicate that the impact of introducing a T&T and S/F solution will in the same proportion affect smoking prevalence, the number of people that will continue smoking, and intensity of smoking, that is quantity consumed. Considering that $\sim 65\%$ of the total consumption of tobacco in the EU comes from those Member States with high-incomes¹³⁴, we estimated that those consumers that would have purchased and consumed the lower priced illicit tobacco products that were removed from the market as a result of implementing a

¹³¹ Project Sun - A study of the illicit cigarette market in the European Union – KPMG, 2013

¹³² Economic Analysis of the EU market of tobacco, nicotine and related products – Matrix Insight, 2013

¹³³ WHO Tob Tax Capacity Building Workshop – Dublin, Ireland; February 2012; World Bank Economics of Tobacco Toolkit – Economic Analysis of Tobacco Demand

¹³⁴ Project Sun - A study of the illicit cigarette market in the European Union – KPMG, 2013

tobacco traceability solution, would now be faced with the decision to instead purchase the (higher-priced) legitimate product:

- Some 60% would purchase the legitimate product, increasing legal tobacco sales by 221.4 M packs (559bn sticks x 20 sticks/pack x 1.32% illicit market addressed x 60%); and
- 40% would choose to reduce their demand and not purchase the higher priced legitimate product, leading to an effective reduction in consumption of 147.6 M packs (559bn sticks x 20 sticks/pack x 1.32% illicit market addressed x 40% price elasticity of demand effect).

In calculate the number of people that will quit or reduce smoking with a reduction of 0.53% (1.32% illicit market addressed x 40% price elasticity of demand effect) in overall consumption, the project team based the analysis on the European Commission data that states that 28% of EU adult population are smokers¹³⁵.

If we calculate the number of people that smoke in the EU, taking into consideration that the total EU population is 503 M people and 425 M people are over 15+ (84.6% of total EU population)¹³⁶, the number of smokers in the EU was 119 million in 2013. Assuming that tobacco consumption reduction impacts directly the number of smokers, the number of people that will quit smoking after 0.53% reduction on tobacco consumption is equal to 0.6 M people.

11.4.1.2 INCREASE IN TAX REVENUE FROM NEW LEGAL TOBACCO

To estimate the impact on taxes resulting from a reduction of overall illicit consumption, the project team used the following initial drivers:

- Number of new sales resulting from a reduction of illicit trade. As seen in section 6.4.1.2, a reduction of illicit trade would mean 221.4 M packs sold in the legal market.
- Average public revenue from taxes on tobacco consumption (excise duties and similar charges) other than VAT, estimated per pack. According to the 2013 excise duty tables published by the European Commission¹³⁷, total revenues from taxes on tobacco consumption (excise duties and similar charges, in 2013) other than VAT were € 81 124 m for the European Union. Considering taxes on cigarettes only, revenues on tobacco consumption other than VAT were € 71 404 m in 2013. Further detail is shown in Figure 63 below:

¹³⁵ http://ec.europa.eu/health/tobacco/policy/index_en.htm

¹³⁶ Eurostat: people by age group and share of total population

¹³⁷ http://ec.europa.eu/taxation_customs/index_en.htm#

EUROPEAN COMMISSION

	CIGARETTES	CIGARS	CIGARILLOS	OTHER	TOTAL
BELGIUM	1 661.0	12.0	0.0	446.0	2 119.0
BULGARIA	908.0	14.0	0.0	0.0	922.0
CZECH REPUBLIC	1 612.0	3.0	0.0	86.0	1 701.0
DENMARK	1 056.0	6.0	0.0	66.0	1 128.0
GERMANY	12 214.0	122.0	0.0	1 794.0	14 130.0
ESTONIA	161.0	0.0	1.0	4.0	166.0
GREECE	2 503.0	0.0	0.0	0.0	2 503.0
SPAIN	6 351.0	104.0	0.0	654.0	7 109.0
FRANCE	9 784.0	159.0	0.0	1 176.0	11 119.0
CROATIA	474.0	0.0	0.0	0.0	474.0
IRELAND	1 053.0	8.0	0.0	3.0	1 064.0
ITALY	9 890.0	43.0	20.0	424.0	10 377.0
CYPRUS	179.0	2.0	0.0	24.0	205.0
LATVIA	146.0	2.0	0.0	2.0	150.0
LITHUANIA	208.0	2.0	0.0	3.0	213.0
LUXEMBOURG	395.0	1 788.0	0.0	132.0	2 315.0
HUNGARY	839.0	0.0	14.0	233.0	1 086.0
MALTA	69.0	0.0	0.0	3.0	72.0
NETHERLANDS	1 750.0	7.0	0.0	642.0	2 399.0
AUSTRIA	1 662.0	0.0	0.0	0.0	1 662.0
POLAND	4 370.0	0.0	0.0	0.0	4 370.0
PORTUGAL	1 193.0	6.0	0.0	113.0	1 312.0
ROMANIA	0.0	0.0	0.0	0.0	0.0
SLOVENIA	411.0	0.0	0.0	15.0	426.0
SLOVAKIA	636.0	0.0	0.0	0.0	636.0
FINLAND	747.0	18.0	0.0	76.0	841.0
SWEDEN	877.0	6.0	0.0	35.0	918.0
UNITED KINGDOM	10 255.0	101.0	0.0	1 351.0	11 707.0
	71 404.0	2 403.0	35.0	7 282.0	81 124.0

Figure 65– EU Public Revenues from Taxes on Consumption per Country (2013, in M €)

Considering that EU cigarette consumption in 2013 was 559 Bn sticks (27 925 M packs), the project team calculated average public revenues from taxes on consumption for the EU equals to € 2.56 per pack (€ 71 404 m of tax revenues from cigarette sales in 2013 vs. 27 925 M packs sold).

Assuming that this € 2.56 per pack is valid at the European Union level, new sales of 221.4 M packs will create 567 M euros of new public revenues from new legal tobacco sales (other than VAT).

In addition to this increase on revenues from new legal sales of tobacco products, an increase in VAT revenues must be estimated:

- Considering VAT standard rates of the countries with bigger sales in the European Union (Germany – 19%, France – 20%, United Kingdom – 20%, Italy – 22%, Spain – 21%), an average 20% VAT on the European Union can be assumed (see VAT detail per country in Figure 64 below).

EUROPEAN COMMISSION

	VAT in %
BELGIUM	21%
BULGARIA	20%
CZECH REPUBLIC	21%
DENMARK	25%
GERMANY	19%
ESTONIA	20%
GREECE	23%
SPAIN	21%
FRANCE	20%
CROATIA	25%
IRELAND	23%
ITALY	22%
CYPRUS	19%
LATVIA	21%
LITHUANIA	21%
LUXEMBOURG	15%
HUNGARY	27%
MALTA	18%
NETHERLANDS	21%
AUSTRIA	20%
POLAND	23%
PORTUGAL	23%
ROMANIA	24%
SLOVENIA	22%
SLOVAKIA	20%
FINLAND	24%
SWEDEN	25%
UNITED KINGDOM	20%

Figure 66– VAT standard rates by country (source: Wikipedia)

- The Weighted Average Price (WAP price of € 4.59 per pack was calculated for 2013. The WAP for cigarettes calculated by reference to the total value of all cigarettes WAP released for consumption, based on the retail selling price including all taxes, divided by the total quantity of cigarettes released for consumption (source: WAP from EC Excise Duty tables Part III – Manufactured Tobacco and manufacturer estimates for non-EU countries; Project Sun – A study of the illicit cigarette market in the European Union – KPMG, 2013; project team calculations), as seen in Figure 65 below:

EUROPEAN COMMISSION

	WAP Price per 20 cigarettes (2013)	LDS (in Bn sticks, 2013)	LDS in M€ (LDS x WAP 2013)	Average WAP Price per 20 cigarettes
GERMANY	5.02 €	80	19 987 €	
AUSTRIA	4.18 €	13	2 725 €	
BELGIUM	4.88 €	11	2 684 €	
BULGARIA	2.38 €	12	1 369 €	
CYPRUS	4.08 €	1	296 €	
CROATIA	2.70 €	7	906 €	
DENMARK	5.33 €	6	1 586 €	
SLOVAQUIA	2.87 €	7	953 €	
SLOVENIA	3.27 €	4	631 €	
SPAIN	4.30 €	48	10 258 €	
ESTONIA	2.82 €	2	251 €	
FINLAND	4.89 €	4	1 098 €	
FRANCE	6.50 €	48	15 447 €	
GREECE	3.50 €	18	3 231 €	
HUNGARY	3.00 €	9	1 404 €	
IRELAND	8.92 €	3	1 503 €	
ITALY	4.58 €	74	16 955 €	
LATVIA	2.60 €	2	217 €	
LITHUANIA	2.38 €	3	332 €	
LUXEMBOURG	3.95 €	3	675 €	
MALTA	4.07 €	0	94 €	
NETHERLANDS	5.29 €	10	2 711 €	
POLAND	2.80 €	47	6 528 €	
PORTUGAL	3.90 €	10	1 958 €	
UK	8.15 €	36	14 576 €	
CZECH REPUBLIC	2.88 €	20	2 830 €	
ROMANIA	2.81 €	24	3 441 €	
SWEDEN	5.91 €	6	1 735 €	
		507.6	116 379.2	4.59 €

Figure 67– Average WAP per 20 cigarettes calculations

- Assuming a € 4.59 per pack WAP, see also in Figure 64, and assuming that the reduction will be proportional in the Member States, the new LDS as a consequence of 0.79% of new smokers now buying on the legal market (formerly buying on the illicit market, before the T&T + S/F implementation) will mean additional € 1 016 m in new sales (221.4m packs x € 4.59 per pack – source: project team calculations).
- Assuming that the average VAT for the EU is 20% (calculated above), additional VAT from new sales will be up to € 169 m (€ 1 016 m / 1.2 x 0.2 – source: project team calculations).

The combined fiscal revenue benefit resulting from additional sales of legitimate tobacco products is therefore estimated to be € 736 m, comprised of € 567 m additional excise related revenues and € 169 m in additional VAT revenues.

11.4.1.3 IMPACTS ON SOCIETY

The main positive impact of a reduction in tobacco consumption is that public health is improved. People who do not smoke or who eventually stop smoking, are healthier and live significantly longer.

Apart from improved public health (i.e. decreased mortality and longer, healthy life years), reduced tobacco consumption will also lead to lower health care costs and to improved productivity due to fewer cases of absenteeism and premature retirement.

Decreased on-the-job productivity and employee absence, because of smoking related diseases, result in an additional cost factor to employers. Absenteeism costs were calculated using the “lost wages method” (based on the average daily earnings rate for employed persons); the most frequently used method to measure absenteeism costs.

There are studies that analyse the monetary impact of decreased tobacco consumption¹³⁸ shown here in Figure 66:

	Different % reduction in tobacco consumption (in M€)			
	0.53%	1%	2%	5%
Decrease in health care expenditure	134	253	506	1,265
Increased productivity	44	83	165	248
- Due to less early retirement / deaths	32	61	122	183
- Due to less absenteeism	12	22	43	65
Decrease in premature mortality costs	2 739	5 167	10 334	15 501

Figure 68– Social Benefits Impacts Calculation as a Consequence of Tobacco Consumption Reduction

As calculated above, with an estimated price elasticity of demand for tobacco of ~0.4, using the assumption that illicit products sell for half the price of legal tobacco products and with an expected reduction in illicit tobacco of 1.32%, it is expected that the net reduction in tobacco consumption would be approximately 0.53%. As shown in the table above, this is expected to translate to reduced public health care expenditures of approximately € 134 m per annum.

11.4.2 TRACEABILITY COST ANALYSIS

11.4.2.1 METHODOLOGICAL APPROACH

The solution costs considered in the analysis are:

- Installation of marking / label applicator equipment on production lines,
- Line monitoring equipment,
- Monitoring / scanning equipment required for data aggregation,
- Estimated cost for system development effort for manufacturers to provide information required for aggregation (packs, cartons, master cases and pallets),
- Cost for compliance monitoring activities, and
- User groups – for different users – training requirements and associated costs for each agent on the supply chain.

In assessing the above costs, both fixed and operating cost elements for implementation and operation of the solution were included:

- Investment costs (CAPEX) associated with implementation of equipment at manufacturing sites, production lines and within the distribution chain. Also included was the required technical infrastructure for data exchange and implementation of the required data storage (repository).
- Operating costs (OPEX) associated with marking items, packaging materials and associated per-unit costs incurred for process and business activities required to

¹³⁸ European Commission – Impact Assessment for a Directive of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products

enable the traceability solution. Further, operating costs associated with the information technology infrastructure were considered.

Information on current market and manufacturing facilities in each Member State was obtained from commercial and public research sources (Euromonitor, Eurostat, reports prepared by private companies). This information was partially confirmed by means of a survey to Member States (that included responses collected from relevant Excise agencies) in regards to its validity and plausibility. Similarly, information on production volumes, import and export volumes per country was obtained from research sources and validated with the respective agencies.

The cost benefit analysis took into account that some of the Member States have existing tax stamp programmes where current processes / equipment could potentially be adapted or reused in the implementation of a traceability solution. However, it is worth noting that the requirements for a FCTC compliant marking is distinct from typical tax stamp programmes, and requires marking of manufactured products for export (which normally would be excluded from a tax stamp programme).

The primary concerns with the detailed bottom-up cost estimate approach were the multitude of variations in tobacco line configurations that would affect equipment costs. Therefore, as an alternative approach, the project sought cost estimates from the DCTA, (whose members already had some experience implementing pack-level marking) to establish an average per line cost (distinguishing between medium speed and high speed production lines). These costs would be used to establish a baseline cost (for Option 1), from which the variations to this of Option 2, 3 and 4 could be rationalised (higher, lower or similar to this base cost).

- **Option 1:** The primary information source is DCTA who provided the project team with data based on its experience implementing this option for several tobacco production lines:
 - Sourced from DCTA were cost estimates for outfitting a production line for pack level tracking, together with pack-to-carton, carton-to-master case and master case-to-pallet aggregation. This included all the required hardware including printers, cameras (vision systems) and aggregation equipment. Distinctions were made between high-speed production lines and medium/low speed production lines.
 - Using estimates of production capacity in the EU to determine the number of production lines and using this to extrapolate the base production line cost.
 - Further, DCTA provided contact information of distributors they had worked with previously on a tobacco traceability pilot in the distribution chain. However, while multiple attempts were made to contact these distributor organisations, only limited feedback was received. As a result, the project had to develop several assumptions instead, as outlined in the following sections.
 - In addition, the estimated cost for the direct marking of packs (unitary costs related to the T&T + S/F marking only individual items: packs, master cases, pallets, etc.) was requested on the survey as a separate line item (as an input for Option 4).
- **Option 2:** The rationale is that similar equipment and hardware would be required for this solution, and therefore the base costs for Option 1 is used as a basis. It is anticipated that solution provider(s) implementing a solution for the EU would benefit from some economies of scale (hardware, software and implementation experience), and at the same time expecting additional overhead cost associated with a service provider providing independent oversight and a profit component. Whilst competitive bidding places pressure on reducing these

margins, the cost benefit analysis makes an allowance for a net higher cost effect of Option 2 over the cost of Option 1.

- **Option 3:** Assumed to be the base cost, but with some duplication of equipment and implementation costs as a result of Member States making independent choices resulting in a sub-optimal implementation, development and allocation of the required solution components.
- **Option 4:** Assumed to be the base cost of Option 1 less the costs associated with the equipment required for direct marking of products on the production line (coupled with the cost of the security feature associated with this option).

The data storage costs were calculated and estimated as a separate exercise (estimated data volumes were calculated, and an estimated storage charge service cost applied to this volume).

Key inputs considered in the analysis from stakeholders are shown in Figure 67 below:

Manufacturers	Distributors	Data Provider	Others
<ul style="list-style-type: none"> ▪ Identify traceability Implementation Cost (requested from DCTA) ▪ Identify traceability operating cost 	<ul style="list-style-type: none"> ▪ Implementation cost to integrate with ERP systems of large distributor ▪ Implementation operational costs ▪ Additional business process time ▪ GS1 registration costs 	<ul style="list-style-type: none"> ▪ Model data storage size ▪ Data storage size cost (considering available online commercial storage / hosting services) 	<ul style="list-style-type: none"> ▪ Market size (consumption, sales, etc.) ▪ Tobacco elasticity of demand ▪ Estimated price of illicit vs. licit tobacco ▪ Approximate tax rate per member state ▪ Tax as % of GDP ▪ Estimated NCD (Non communicable disease) health costs (EPCIS model)

Figure 69– Key Inputs from Stakeholders for the cost-benefit analysis

The analysis considered that registration costs were already incurred in the manufacturing industry so impacts were only considered in the distribution chain.

11.4.2.2 RATIONAL AND CALCULATIONS

In the traceability cost analysis, three main stakeholders were considered: manufacturers, distribution chain operators (wholesalers and other distributors) and Member States authorities. Each of them will endure cost impacts at different levels. The costs have been split between one-off costs and on-going costs as shown in Figure 68 below:

One-off costs	On-going costs
<ul style="list-style-type: none"> ▪ Pack printer and installation ▪ Aggregation: <ul style="list-style-type: none"> ○ Pack-to-carton ○ Carton to shipping case ▪ Carton printing, with applicator ▪ Case label printing ▪ Pallet label printer ▪ Server and software: <ul style="list-style-type: none"> ○ Factories ○ Warehouses ○ Mobile sales forces ○ Vending machine service vans ▪ Utrack kit (PC + 2 scanners and related software) ▪ Other installation local support not included above ▪ IT System development 	<ul style="list-style-type: none"> ▪ Packaging and labelling: <ul style="list-style-type: none"> ○ Packs ○ Cartons ○ Master cases ○ Pallets ▪ Server and software maintenance ▪ Global traceability database: <ul style="list-style-type: none"> ○ Hosting ○ Maintenance ▪ Additional HR costs ▪ Registration costs ▪ IT System maintenance <hr style="border-top: 1px dashed black;"/> <ul style="list-style-type: none"> ▪ Depreciation

Figure 70– Split between One-off Costs and On-going Costs

All of these costs are related to one (or more) of a set of core activities, including:

- Master data management and processing,
- Printing / marking,
- Reading / scanning,
- Auditing / controlling, and
- Reporting.

11.4.2.2.1 MANUFACTURERS

The proposed approach obtained cost estimates from the existing DCTA implementations as a base (for Option 1), and then rationalised the variations to this (higher, lower or similar to this base cost) for the subsequent options. This section is structured as follows:

- Traceability cost analysis for Option 1.
- Identify and quantify variations in Options 2 to 4 versus Option 1.

11.4.2.2.2 COST ANALYSIS FOR TRACEABILITY SOLUTION OPTION 1

Traceability cost analysis for Option 1 was structured into four main steps:

- Estimate the number of manufacturing companies, manufacturing facilities and production lines within the European Union,
- Identify which costs impact on Option 1,
- Define unitary costs, and
- Quantify cost impact and estimate at EU level.

11.4.2.2.2.1 *Number of manufacturing companies, manufacturing facilities and production lines within the European Union estimation.*

The same analysis was carried out to estimate the number of **manufacturing facilities** within the EU. According to NOMISMA (2012), 362 tobacco manufacturing facilities were estimated in 2010. Again, considering that the overall market decreased 8.4% in the 2010 – 2013, analysis assumed that the number of manufacturing facilities in the EU reduced as well, bringing the total number of manufacturing facilities in the EU to 332 in 2013.

The project distributed a survey to tobacco manufacturers in the EU (distributed through four industry associations). The production line figure calculation was done based on an extrapolation using information from the survey responses from three of the top four manufacturing companies operating in the EU. These companies represent ~72% of the total EU market.

The following assumptions were made:

- Cigarette market in the European Union is, by far, the biggest business segment of the tobacco industry. This, together with limited information related to manufacturers facilities and production lines of 'other tobacco products', made the contracting team to consider the cigarette and cigar market only for the purpose of estimating T&T costs.
- Data received from the three large manufacturers is representative of the total market, taking into account a mix of high-speed and medium/low speed production lines,
- Only the big four tobacco companies would operate high-speed production lines. Small and medium size companies would operate low and medium speed production lines,
- Low and medium speed production lines present same average costs, with no significant variances between them,
- High-speed lines are considered to produce more than 800 packs per minute, and
- Low and medium speed production lines produce less than 800 packs per minute.

Using these assumptions, and extrapolating from the survey responses from three of the largest manufacturers, the total estimated number of production lines for the EU cigarette manufacturing industry:

- 697 low and medium speed production lines, and
- 46 high speed production lines.

The impact of the four proposed traceability solutions on cigar manufacturers was also assessed as a separate exercise (Please refer to the end of the sub-section 6.4.2.2.3).

11.4.2.2.2.2 *Costs impacting on Traceability Option 1 identification*

An analysis of which cost could impact the P&L of a manufacturing company was done by the project team, identifying whether:

- CAPEX vs. OPEX, and
- Costs impact at facility level or production line level.

As shown in Figure 69 below:

<i>CAPEX - production line</i>	Option 1
Pack printer & installation (laser)	✓
Aggregation - pack to carton, carton to shipping case	✓
Carton printing	✓
Case label printing	✓
Installation local support not included above	✓
<i>CAPEX - facilities</i>	
Pallet label printing	✓
Factory server and software	✓
Utrack kit (PC + 2 scanners)	✓
<i>OPEX</i>	
Global T&T database: hosting and maintenance	✓
Packaging & labelling	✓
Factory server and software maintenance	✓
Annual depreciation	✓

Figure 71– Manufacturers P&L: Cost Impacts Identification

Unitary Costs Definition

- Information received from the industry survey helped to define unitary costs for each cost identified, differentiating costs for low and medium speed production lines and high-speed production lines. When this information was not enough to achieve a minimum level of representation, consultations with the market were performed by the team. Costs that impact at manufacturing facilities level were as follows:
 - Pallet label printing: € 3 000
 - Factory server and software: € 15 000
 - Utrack kit (PC + 2 scanners - two handheld scanners that can be used for reading and recording traceability markings on tobacco items and packaging, as well as a workstation for uploading data from the scanning devices. Includes both hardware and software): € 10 000

Costs that impact production line levels considered range for both high speed production lines and low and medium speed production lines (source: industry survey). An average cost was calculated for each range, as shown in Figures 70 and 71 below:

<i>High speed production lines</i>	Min	Max	Average
Pack printer & installation (laser)	290 000 €	355 000 €	322 500 €
Aggregation - pack to carton, carton to shipping case	63 270 €	63 270 €	63 270 €
Carton printing	112 166 €	112 166 €	112 166 €
Case label printing	11 340 €	11 340 €	11 340 €
Installation local support not included above	15 000 €	15 000 €	15 000 €
	491 776 €	556 776 €	524 276 €

Figure 72– Manufacturers Average Costs for High Speed Production Lines

<i>Low and medium speed production lines</i>	Min	Max	Average
Pack printer & installation (laser)	30 000 €	57 000 €	43 500 €
Aggregation - pack to carton, carton to shipping case	51 000 €	51 000 €	51 000 €
Carton printing	6 000 €	13 000 €	9 500 €
Case label printing	4 750 €	4 750 €	4 750 €
Installation local support not included above	10 000 €	10 000 €	10 000 €
	101 750 €	135 750 €	118 750 €

Figure 73– Manufacturers Average Costs for Low and Medium Speed Production Lines

- On-going costs:
 - Packaging and labelling: unitary costs of € 0.0021 / label as identified on the European Commission document¹³⁹.
 - Factory server and software maintenance assumed to be 10% annual expenses over investment incurred (team estimation).
 - Annual depreciation calculated on a 6-year life of the investment incurred (team estimation).

a) Cost impact of traceability Option 1 - quantification.

- Cost impacts on manufacturer’s production lines and calculation rational as follows (see Figure 72 below):

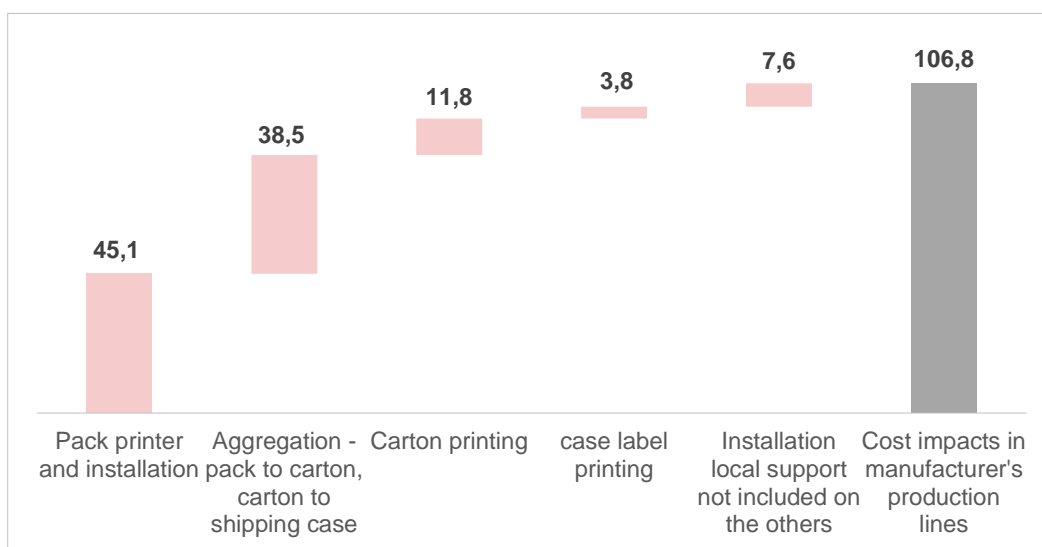


Figure 74 – Cost Impacts in Manufacturer’s Production Lines (CAPEX, in M euros, 2013)

- Pack printer and installation (laser – CAPEX) = € 45.1 m euros every 6 years
 - Related to low and medium speed production lines = € 30.3 m euros (697 low and medium speed production lines in the EU x € 43 500 - average price considered).
 - Related to high speed production lines = € 14.8 m (46 high speed production lines in the EU x € 322 500 - average price considered).
- Aggregation – pack-to-carton, carton-to-shipping case (CAPEX) = € 38.5 m every 6 years
 - Related to low and medium speed production lines = € 35.6 m (697 low and medium speed production lines in the EU x € 51 000 - average price considered).
 - Related to high speed production lines = € 2.9 m (46 high speed production lines in the EU x € 63 270 m - average price considered).

¹³⁹ European Commission – Impact Assessment for a Directive of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products

- Carton printing (CAPEX) = € 11.8 m every 6 years
 - Related to low and medium speed production lines = € 6.6 m (697 low and medium speed production lines in the EU x € 9 500 - average price considered).
 - Related to high-speed production lines = € 5.2 m (46 high speed production lines in the EU x € 112 166 - average price considered).
- Case label printing (CAPEX) = € 3.8 m every 6 years
 - Related to low and medium speed production lines = € 3.3 m (697 low and medium speed production lines in the EU x € 4 750 - average price considered).
 - Related to high speed production lines = € 0.5 m (46 high speed production lines in the EU x € 11 340 - average price considered).
- Installation local support not included above (CAPEX) = € 7.6 m every 6 years.
 - Related to low and medium speed production lines = € 6.9 m (697 low and medium speed production lines in the EU x € 10 000 - average price considered).
 - Related to high speed production lines = € 0.7 m (46 high speed production lines in the EU x € 15 000 - average price considered).
- Cost impacts in manufacturer's facilities and calculation rational as follows (see Figure 73 below):

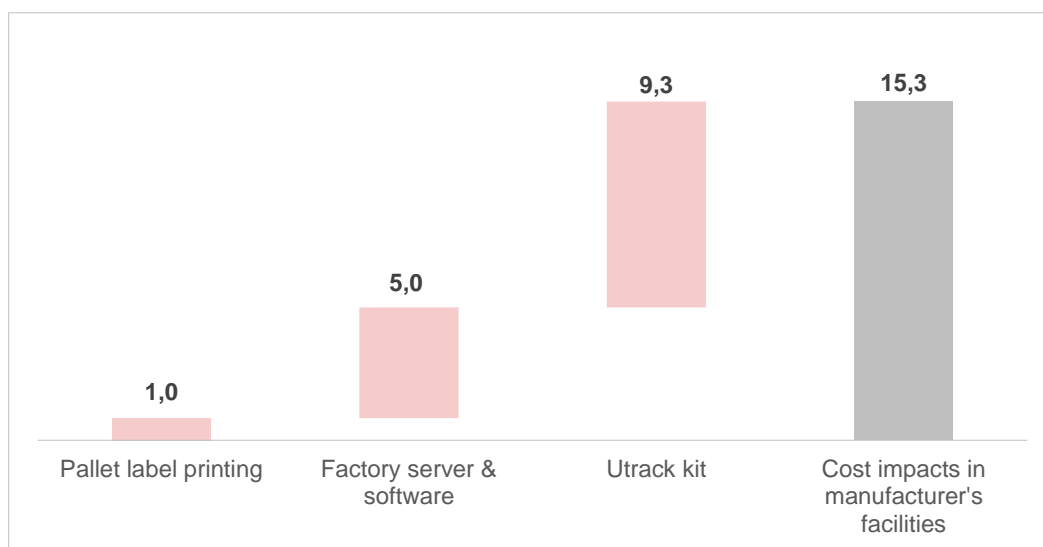


Figure 75- Cost Impacts in Manufacturer's Facilities (CAPEX, in M euros)

- Pallet label printing (CAPEX): € 1.0 m, every 6 years
 - 332 manufacturing facilities in the EU x € 3 000 (unitary cost each pallet label, one per facility).
- Factory server and software (CAPEX): € 5.0 m, every 6 years
 - 332 manufacturing facilities in the EU x € 15 000 (unitary cost for each factory server, one per facility).
- Utrack kit (PC 2 scanners - CAPEX) = € 9.3 m, every 6 years.

- Team assumed that 40% of the manufacturing facilities were 'big' and they will need up to four Utrack kit packs. Other 60% will require only two kits per facility.
- Big manufacturing facilities Utrack kit costs = € 5.3 m (CAPEX)
 - 133 (big manufacturing facilities, 40% over total EU) x 4 (number of Utrack kits required on big warehouses) x € 10 000 (unitary cost for each Utrack kit).
- Small and medium warehouses Utrack kit costs = € 4.0 m (CAPEX).
 - 199 (small & medium warehouses, 60% over total EU) x 2 (number of Utrack kits required on big warehouses) x € 10 000 (unitary cost for each Utrack kit).
- Variable costs impacting in manufacturing industry and calculation rational as follows (see Figure 74 below):

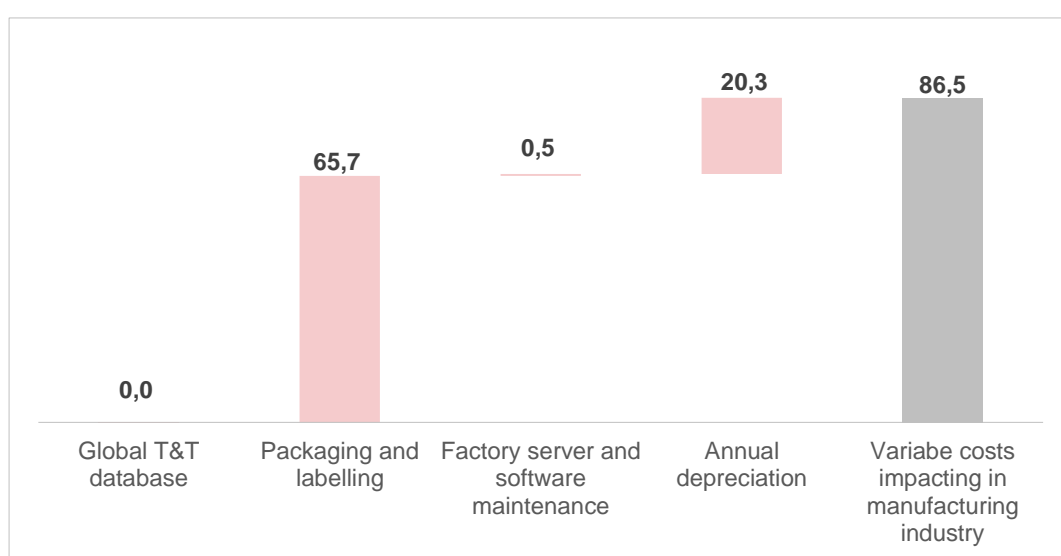


Figure 76– Variable Cost Impacting in Manufacturing Industry (OPEX, in M euros)

- Global traceability database (OPEX): hosting and maintenance = € 6.2 k / year. Pricing received from industry consider costs that impact at manufacturing company level (Azure). Prices per storage capacity and redundancy are shown in Table 43, but it is expected that negotiations with supplier could lead to savings (up to 10-15% over PVP).

Storage capacity (€/Gb)	LRS	ZRS	GRS	RA-GRS
First 1 TB / month	0.0179 €	0.0224 €	0.0358 €	0.0455 €
Next 49 TB (1 to 50 TB) / month	0.0176 €	0.0220 €	0.0352 €	0.0447 €
Next 450 TB (50 to 500 TB) / month	0.0173 €	0.0216 €	0.0346 €	0.0439 €
Next 500 TB (500 to 1.000 TB) / month	0.0170 €	0.0213 €	0.0340 €	0.0432 €
Next 4.000 TB (1.000 to 5.000 TB) / month	0.0167 €	0.0209 €	0.0334 €	0.0424 €
Over 5.000 TB / month	On demand	On demand	On demand	On demand

Table 43– Storage Data Base Pricing – Azure System

For reference, please find below several types of data storage redundancy options that have cost implications:

- Locally redundant storage (LRS) maintains three copies of the data. LRS is replicated three times within a single facility in a single region. LRS protects data from normal hardware failures, but not from the failure of a single facility.
- Zone-redundant storage (ZRS) maintains three copies of the data. ZRS is replicated three times across two to three facilities, either within a single region or across two regions, providing higher durability than LRS. ZRS ensures that data is durable within a single region.
- Geo-redundant storage (GRS) is enabled for storage account by default when it is created. GRS maintains six copies of the data. With GRS, data is replicated three times within the primary region, and is also replicated three times in a secondary region (considerable distance from the primary region), providing the highest level of durability. In the event of a failure at the primary region, Azure Storage will failover to the secondary region. GRS ensures that data is durable in two separate regions.
- Read-access geo-redundant storage (RA-GRS) provides all of the benefits of geo-redundant storage noted above, and also allows read access to data at the secondary region in the event that the primary region becomes unavailable. Read-access geo-redundant storage is recommended for maximum availability in addition to durability.

For maximum durability, the supplier recommends using geo-redundant storage; for calculation purposes we have used the corresponding price (€ / Gb).

Data storage needed at an European Union level was calculated using industry figures for complying with TPD's Article 15 (2) requirements and can be found in Figure 75 below:

Projected data sizes for the EU market

		Packs	KiB
Market Size	Domestic consumption	28,000,000,000	1,990,765,000
	Est. Export (EUR 1.4 bn)	4,361,370,717	310,088,006
	Est. Imports (EUR 250 m)	806,451,613	57,337,702
	Total	33,167,822,329	2,358,190,708
Data size (/ annum)		TiB	2.20
Data size (/ annum + 30% overhead)		TiB	2.86
Data size (7 years)		TiB	19.99

Figure 77– Estimated EU wide Data Storage Needs Calculation

Details on how has the contracting team calculated the information stored per pack can be found in Table 41, page 269 and pertaining footnotes.

Annual costing of a global traceability database was then calculated as follows (see Figure 76 below):

Storage capacity (€/Gb)	LRS	ZRS	GRS	RA-GRS
First 1 TB / month	220.0 €	275.3 €	439.9 €	559.1 €
Next 49 TB (1 to 50 TB) / month	2 889.4 €	3 611.8 €	5 778.8 €	7 338.5 €
Next 450 TB (50 to 500 TB) / month				
Next 500 TB (500 to 1.000 TB) / month				
Next 4.000 TB (1.000 to 5.000 TB) / month				
Over 5.000 TB / month				
	3 109.4	3 887.0	6 218.7	7 897.6

Figure 78– EU wide Data Storage Costs Calculation Based on Azure Pricing

GRS (Geo-redundant storage) total costs for hosting and maintaining a global traceability solution are € 6 k / year for all 230 manufacturing companies in the European Union.

- **Note:** This cost quotation covers data storage. However, there is an additional cost component related to operating a repository supporting the EPCIS standards, as discussed previously in this report. Assumptions related to these costs have been included a part of 11.4.2.2.5 below.

Whereas a decision is not supposed to be made at this stage in regards physical location of the data storage facility, beyond requirement that this be located within the EU, the project team asked providers and confirmed that this requirement is fully covered. Further in this document, under 11.4.2.2.5, we also refer to server hosting, and to cost estimates that consider data and application hosting services to be provided within the EU [aligned to requirements of TPD Article 15 (8)]. For this cost assessment, cost estimates for hosting in Ireland were used.

In addition to these data storage costs there is a number of additional hardware and software costs to consider, as the next Table 44 shows, again taken from Azure:

Cost items	Qty	Cost	
		Monthly €	Annual €
Windows virtual machines to run Oracle software (A8 specs)	4	5,429.76	65,157.12
Oracle weblogic server software to receive T&T data (A8 specs)	2	8,388.42	100,661.04
Oracle database servers (A8 specs)	2	16,710.36	200,524.32
2 Tb Bandwidth costs		129.26	1,551.12
5 Tb Backup costs		743.96	8,927.52
VPN gateway for 744 hours/month		272.00	3,264.00
Total cost		31,673.76	380,085.12

Table 44– Additional EU wide Data Storage Related Costs Calculation Based on Azure Pricing

Given its materiality in light of the overall costs, we have not included them within the cost benefit analysis tables/figures in this report.

Maintenance costs for the tracking and trace software, as described in section 11.4.2.2.5.1, are also to be added, and an assumption of 15% on an yearly basis was considered:

- Packaging and labelling costs (OPEX) = € 65.7 m per year

- Unitary costs of € 0.0021 per label x number of units to be marked in 31.3 M units (without considering the labelling of cartons, cases and pallets; if so, units to be marked would be 33.1M and OPEX equals to 69.5M€)
- Factory server and software maintenance costs (OPEX) = € 0.5 m per year
 - 10% annual maintenance costs x € 5.0 m (server and software costs)
- Annual depreciation (OPEX) = € 20.3 m per year
 - € 122.1 m investment depreciated over 6 year life time
 - Investments considered:
 - Pack printer & installation (laser) = € 45.1 m
 - Aggregation – pack-to-carton, carton-to-shipping case = € 38.5 m
 - Carton printing = € 11.8 m
 - Case label printing = € 3.8 m
 - Installation local support not included above = € 7.6 m
 - Pallet label printing = € 1.0 m
 - Factory server and software = € 5.0 m
 - Utrack kit (PC 2 scanners and software) = € 9.3 m

b) Traceability Solution Option 1 cost impacts summary

Annualized total costs (OPEX + depreciation) estimated for traceability Option 1 are equal to € 86.5 m (€ 0.0027 / unit to be marked). Investment costs for production line took into account different unitary costs between high-speed vs. low and medium speed production lines. Further detail is explained in Figure 78 below:

EUROPEAN COMMISSION

<i>CAPEX by PRODUCTION LINE</i>		Costs (in €)
Pack printer & installation (laser)		45 110 417 €
Aggregation - pack to carton, carton to shipping case		38 458 208 €
Carton printing (with applicator 13,000)		11 764 553 €
Case label printing		3 831 556 €
Installation local support not included above		7 659 722 €
		106 824 456 €

<i>CAPEX by FACILITY</i>		
Pallet label printing		994 776 €
Factory server and software		4 973 880 €
Utrack kit (PC 2 scanners) - BIG facilities		5 305 472 €
Utrack kit (PC 2 scanners) - SMALL & MEDIUM facilities		3 979 104 €
		15 253 232 €

<i>OPEX</i>		
Global T&T database: hosting and maintenance		6 219 €
Total packaging and labelling		65 693 799 €
Factory server and software maintenance		497 388 €
Annual depreciation		20 346 281 €
		86 543 687 €

<i>Sum up</i>		
CAPEX		122 077 688 €
OPEX (with no annual depreciation)		66 197 405 €
Additional costs (OPEX)		0 €
TOTAL (OPEX + CAPEX + additional costs)		188 275 093 €
Annual depreciation		20 346 281 €
Annualized total costs (OPEX + depreciation)		86 543 687 €
Average € / unit to be marked		0.0026 €
Average € / distribution point		260 994 €

Figure 79: Traceability Solution Option 1 Cost Impacts Calculation for Manufacturers

11.4.2.2.3 OPTIONS 2 - 4 VERSUS OPTION 1

11.4.2.2.3.1 Identify and quantify variations between traceability solution Options 1 and 2.

The methodological approach for Option 2 rationalises that similar equipment and hardware is required for this solution, and therefore base costs for Option 1 could be used. It is anticipated that solution provider(s) implementing a solution for the EU would benefit from some economies of scale (hardware, software and implementation experience), and at the same time, expecting an additional overhead cost associated with a service provider providing independent oversight and a profit component. Whilst competitive bidding places pressure on reducing these margins, the cost benefit analysis makes an allowance for a net higher cost effect of Option 2 over the cost of Option 1. An indicative net positive cost increase of a 10% margin was made for calculation purposes, which should be considered indicative, representing an additional amount of € 8.6 m for traceability Option 2 (vs. Option 1).

Apart from this additional margin already considered, there are no other significant differences between traceability Option 1 and traceability Option 2 costs.

Annualized total costs (OPEX + depreciation) estimated for traceability Option 2 are equal to € 95.2 m (€ 0.0030 / unit to be marked). A cost comparison between Options 1 and 2 is displayed in Figure 79 below, where cost differences are highlighted with a red dotted box:

	OP1	OP2
CAPEX by PRODUCTION LINE	106,824,456 €	106,824,456 €
CAPEX by FACILITY	15,253,232 €	15,253,232 €
OPEX	86,543,687 €	86,543,687 €
Other additional costs	-	8,654,369 €

	Sum up	OP1	OP2
CAPEX		122,077,688 €	122,077,688 €
OPEX (with no annual depreciation)		66,197,405 €	66,197,405 €
Additional costs (OPEX)		-	8,654,369 €
TOTAL (OPEX + CAPEX + additional costs)		188,275,093 €	196,929,462 €
Annual depreciation		20,346,281 €	20,346,281 €
Annualized total costs (OPEX + depreciation)		86,543,687 €	95,198,055 €
Average € / unit to be marked		0.0026 €	0.0029 €
Average € / distribution point		260,994 €	287,094 €

Figure 80: Traceability Solution Option 2 vs. 1 Cost Impacts Calculation for Manufacturers

11.4.2.2.3.2 Identify and quantify variations between traceability Options 1 and 3.

The methodological approach for Option 3 assumes the base cost associated with Option 1, but with some duplication of equipment as a result of Member States making independent choices resulting in a sub-optimal implementation and allocation of equipment.

In Option 3, a single data management repository is considered for each Member State. It will be based on blend traceability Option 1 and traceability Option 2 (some Member States will choose industry and others solution providers). Considering there are 22 manufacturing Member States, the project used an estimate of 22 possible different repositories. Option 3 will present higher costs due to the increased need of compatibility considerations between countries, and it is anticipated that this will directly impact core traceability solution activities identified.

Core activities	Impact
Mega data management	Very high
Printing / marking	Low
Reading / scanning	Low
Auditing / controlling	Very high
Reporting	High

Annualized total costs (OPEX + depreciation) estimated for traceability Option 3 are equal to € 109.0 m (€ 0.0034 / unit to be marked). A cost comparison between Options 1 and 3 is included in Figure 80 below, where cost differences are highlighted with a red dotted box (Option 3 presents higher costs due to bigger need of compatibility requirements between countries: about 25% higher costs):

	OP1	OP3
CAPEX by PRODUCTION LINE	106,824,456 €	106,824,456 €
CAPEX by FACILITY	15,253,232 €	15,253,232 €
OPEX	86,543,687 €	86,543,687 €
Other additional costs	-	22,501,359 €

	OP1	OP3
<i>Sum up</i>		
CAPEX	122,077,688 €	122,077,688 €
OPEX (with no annual depreciation)	66,197,405 €	66,197,405 €
Additional costs (OPEX)	-	22,501,359 €
TOTAL (OPEX + CAPEX + additional costs)	188,275,093 €	210,776,452 €
Annual depreciation	20,346,281 €	20,346,281 €
Annualized total costs (OPEX + depreciation)	86,543,687 €	109,045,045 €
Average € / unit to be marked	0.0026 €	0.0033 €
Average € / distribution point	260,994 €	328,853 €

Figure 81: Traceability Solution Option 3 vs. 1 Cost Impacts Calculation for Manufacturers (additional compatibility requirements and resulting overhead between countries in Option 3 represent 25% higher costs vs. Option1)

11.4.2.2.3.3 Identify and quantify variations between traceability Options 1 and 4.

The methodological approach for Option 4: assumed to be the base cost less the price of direct marking (coupled with the cost of the security feature associated with this option). In terms of data storage, Option 4 presents the same characteristics of Option 3.

This means that costs related to the traceability option will be significantly smaller because there will be some costs that will be integrated with the security features solution (in other words – while there is less capital equipment to be installed at each manufacturing facility, there is an additional cost related to the security feature in order for it to include a unique identifier). At the same time, this means that traceability Option 4 cannot be considered individually *per se* and will always have to be accompanied by security features Option 4.

Considering the impact on the core activities, we see that printing and reading are directly affected (costs will be integrated in the security features solution) by this solution:

Core activities	Impact
Master data management	Low
Printing / marking	High
Reading / scanning	High
Auditing / controlling	Low
Reporting	Low

Annualized total costs (OPEX + depreciation) estimated for traceability Option 4 are equal to € 13.4 m (€ 0.0004 / unit to be marked). A cost comparison between Options 1 and 4 is presented in Figure 81 below, where cost differences are highlighted with a red dotted box:

EUROPEAN COMMISSION

Pack printer & installation (laser)	45,110,417 €	-
Aggregation - pack to carton, carton to shipping case	38,458,208 €	38,458,208 €
Carton printing (with applicator 13,000)	11,764,553 €	11,764,553 €
Case label printing	3,831,556 €	3,831,556 €
Installation local support not included above	7,659,722 €	7,659,722 €
	106,824,456 €	61,714,039 €

CAPEX by FACILITY

Pallet label printing	994,776 €	994,776 €
Factory server and software	4,973,880 €	4,973,880 €
Utrack kit (PC 2 scanners) - BIG facilities	5,305,472 €	5,305,472 €
Utrack kit (PC 2 scanners) - SMALL & MEDIUM facilities	3,979,104 €	3,979,104 €
	15,253,232 €	15,253,232 €

OPEX

Global T&T database: hosting and maintenance	6,219 €	6,219 €
Total packaging and labelling	65,693,799 €	121,607 €
Factory server and software maintenance	497,388 €	497,388 €
Annual depreciation	20,346,281 €	12,827,878 €
	86,543,687 €	13,453,092 €

Sum up

CAPEX	122,077,688 €	76,967,271 €
OPEX (with no annual depreciation)	66,197,405 €	625,213 €
Additional costs (OPEX)	-	-
TOTAL (OPEX + CAPEX + additional costs)	188,275,093 €	77,592,484 €
Annual depreciation	20,346,281 €	12,827,878 €
Annualized total costs (OPEX + depreciation)	86,543,687 €	13,453,092 €
Average € / unit to be marked	0.0026 €	0.0004 €
Average € / distribution point	260,994 €	40,571 €

Figure 82: Traceability Solution Option 4 vs. 1 Cost Impacts Calculation for Manufacturers

In regards to cigar manufacturing – that represent 2.9% of total tobacco market (in volume) – estimates from an industry association indicate 550 finishing stations are in operation for the EU. Taking this data into account, an additional cost impact on cigar manufacturers was assessed as a separate exercise (see Figure 82). Annual costs impacting cigar manufacturers and the calculation rationale are as follows:

- Packaging and labelling costs (OPEX) = € 2.4 m per year
 - Unitary costs of € 0.0021 per label for number of units to be marked in 959 M units, 144 M trays and 7 M “master cases”.
- Annual depreciation (OPEX) = € 0.92 m per year
 - € 5.5 m investment on Utrack kit (PC + 2 scanners and related software) for 6 years life time on investment realized, considering 550 finishing stations.
- Note: The packaging and labelling costs related to the aggregation process – pack-to-carton, carton-to-shipping case – were not included, as data regarding aggregation relationships were not possible to obtain.

	<i>Sum up</i>	Option 1	Option 2	Option 3	Option 4
CAPEX		5,500,000 €	5,500,000 €	5,500,000 €	5,500,000 €
OPEX		2,369,208 €	2,369,208 €	2,369,208 €	322,081 €
TOTAL (OPEX + CAPEX)		7,869,208 €	7,869,208 €	7,869,208 €	5,822,081 €
Annual depreciation		916,667 €	916,667 €	916,667 €	916,667 €
Annualized total costs (OPEX + depreciation)		3,285,875 €	3,285,875 €	3,285,875 €	1,238,748 €

Figure 83: Traceability Solution Cost Impacts Calculation for Cigar Manufacturers

Option 4 seems to have a significantly smaller impact on cigar manufacturers. However, this option only considers the packaging and labelling of 144 M trays and 7 M “master cases”, while costs associated with the marking of the 959 M retail units are integrated with the security feature solution, meaning that Option 4 cannot be considered individually, per se, and will always have to be accompanied by security features costs for Option 4.

11.4.2.2.4 WHOLESALERS AND DISTRIBUTORS

This cost / benefit model takes into consideration three different distribution chain operators within our scope of analysis:

- Large distributors and wholesalers;
- Vending machines service vans; and
- Mobile sales forces.

Analysis was carried out for each operator, sizing each market and identifying the number of facilities or mobile units to be considered in an integrated traceability and security feature solution implementation at the EU level, identifying which costs would impact their P&L and calculating these impacts.

Five different types of impacts were identified, considering possible CAPEX and OPEX expenses: investments in servers and software, investments in technology (Utrack kit PC + 2 scanners and related software), additional operational HR costs, software maintenance and annual depreciation. Each of these will impact each stakeholder differently.

11.4.2.2.4.1 Big distributors and wholesalers cost analysis.

Costs identified the impact on big distributors and wholesalers at two different levels:

- As a distribution company
- At the facilities level

First, we calculated how many distribution companies are currently operating in the European Union. To estimate the number, available data from Eurostat was used, which showed that the number of wholesale companies operating in the tobacco market in the EU was 2 450 in 2012 (see Annexure 10).

Next, an attempt was made to estimate the number of facilities – warehouses and storage locations – but, again, no public data related to the European Union Tobacco Market as a whole was available. As a matter of fact, the project team has managed to get information related to just a small number of individual national markets, as referred to below:

- Spain: 68 facilities (source: CMT - Órgano de Control del Mercado de Tabacos)
- Italy: 175 facilities (source: ETV country report Italia; AGEMOS)
- Portugal: 150 facilities (source: NOMISMA, validated by the industry)

Despite representing ca. 24% of the total European market consumption (based on Project Sun report, 2013 - Italy represents 14%, Spain 9% and Portugal 1%) the countries' specific characteristics cannot necessarily be used as a general representation of the EU tobacco distribution market:

- The Spanish distribution market was liberalized in 2010, before that it was controlled by a single distributor (Logista).
- The Italian market is currently controlled by a single distributor (Logista).

In the European Union there are two other countries with similar characteristics: France (one unique distributor: Altadis) and Bulgaria (one exclusive distributor). Taking this into account, projecting these numbers out to the EU market as a whole was unrealistic, as seen below:

- Driver used: manufactured cigarette consumption (2013, bn sticks):
 - Spain + Italy + Portugal = 172 bn sticks (source: Project Sun report, 2013)
 - Total EU = 559 bn sticks (source: Project Sun report, 2013)
 - Projection of the number of warehouses for the EU market = 1 275
 - Rational: as there are 2 450 wholesaler companies in the EU, it is not acceptable to say that there are 1 275 warehouses only.
- Driver used: area of each of the countries (in km²):
 - Spain + Italy + Portugal = 897 350 km² (source: Wikipedia)
 - Total EU = 4 324 782 km² (source: Wikipedia)
 - Projection of the number of warehouses for the EU market = 1 894
 - Rational: Same as above.

Recognizing that such calculations would not give us a realistic overview of the EU wholesale market and that attempts to identify alternative source of information were unsuccessful, the project team looked for additional insights from other industries to estimate possible figures comparing other markets. Considering that the EU distribution market should have between 6 000 and 8 000 warehouses and that projections should be conservative, the project team calculated the cost impact on the wholesaler distribution channel for 7 690 facilities.

Once the number of large wholesalers and distributors was estimated, our analysis identified which costs impact their Profit & Loss accounts and if it would be at company level or at facility (warehouse) level, as depicted in Figure 83 below:

	Company	Warehouse
I.- Server and software	✓	✗
II.- Utrack kit (PC 2 scanners)	✗	✓
III.- Additional HR costs	✗	✓
IV.- Software maintenance	✓	✗
V.- Annual depreciation	✗	✓
VI.- Registration costs	✓	✗

Figure 84: Costs Identification for Large Wholesalers and Distributors

Items I, IV and VI relate to those impacts on distribution warehouse operators that choose to integrate with the requisite traceability solution functions and requirements into their own current systems, whereas II, III and V relate to those that would simply use the provided solution.

The following unitary costs were considered in the analysis:

- Server and software = € 6 000 (source: industry survey);
- Utrack kit (PC 2 scanners, with related software) = € 10 000 (source: industry survey);
- Additional HR operational costs in warehouses = +20% (team estimation, considering bigger amount of data to be recorded);
- Software maintenance costs = 10% over investment incurred (team estimation);
- Annual depreciation calculated on a 6-year life of the investment realized (team estimation); and
- Registration costs = € 3 000 (project team estimated an annual average costs at European Union level based on GS1 the Global language of business data, source: <http://www.gs1.org/>)

The following calculations reflect the impact for the wholesalers at the European Union level, and are presented into capital expenditure and operational expenditure, the latter including the annual depreciation effect calculated over the estimated investment figures (see Figures 84 and 85 below):

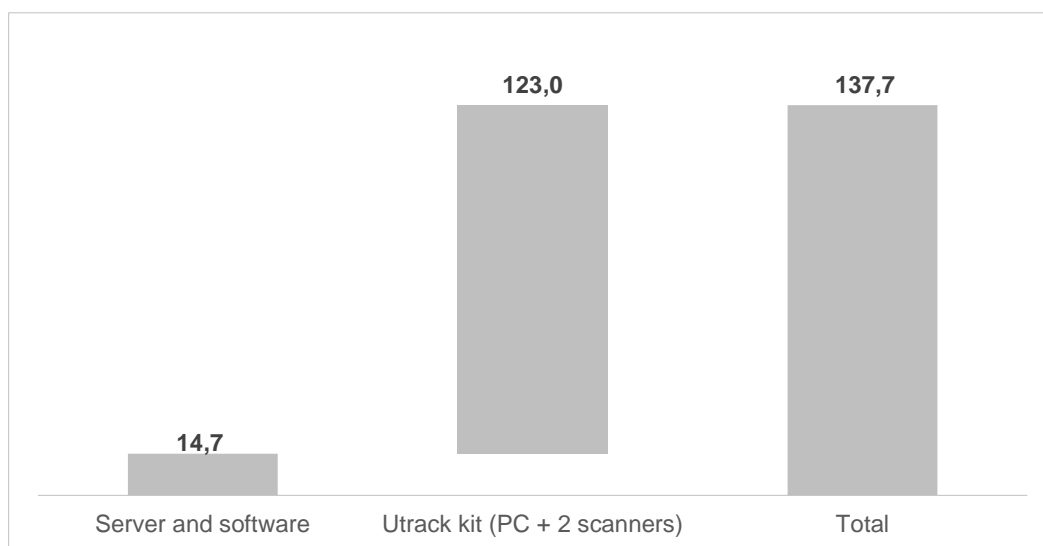


Figure 85– Impacts in wholesalers and big distributors (CAPEX, in M euros)

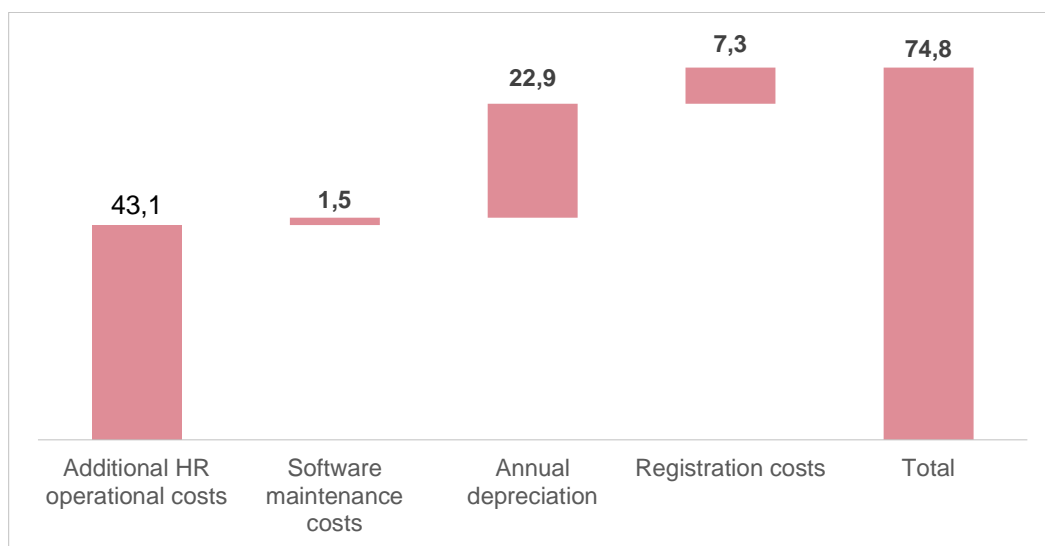


Figure 86– Cost impacts in wholesalers and big distributors (OPEX, in M euros)

- Server and software = € 14.7 m (CAPEX), one-off costs.
 - 6 000 euros (unitary cost for each server and software pack) x 2 450 (number of wholesaler companies in the European Union)
- Utrack kit (PC 2 scanners and related software) = € 123.0 m (CAPEX), to be realized each 6 years.
- The team assumed that 30% of the warehouse facilities were 'big' and they will need up to three Utrack kit packs. Other 70% will require only one kit per facility.
 - Big warehouses Utrack kit costs = € 69.2 m
 - 2 307 (big warehouses, 30% over total EU) x 3 (number of Utrack kits required on big warehouses) x € 10 000 (unitary cost for each Utrack kit)
 - Small and medium warehouses Utrack kit costs = € 53.8 m
 - 5 383 (small & medium warehouses, 70% over total EU) x 1 (number of Utrack kits required on big warehouses) x € 10 000 (unitary cost for each Utrack kit)
- Additional HR operational costs in warehouses = € 43.1 m (OPEX, (see Annexure 10).
 - Number of facilities (per country) x Average 3 people doing shipping operation on each facility x Minimum wages in the EU (per Member State) x Considering 14 wages per year x 20% incremental operational HR costs
- Software maintenance costs = € 1.5 m (OPEX).
 - 10% (annual maintenance costs) x € 14.7 m (server and software costs)
- Annual depreciation = € 22.9 m (OPEX).
 - € 137.7 m (investment in Utrack kits, server and software) / 6 (years life time on investment realized)
- Registration costs = € 7.3 m (OPEX).
 - 2 450 (number of wholesaler companies in the EU in 2013) x € 3 000 (average annual registration costs)

As a result of a competitive tender process, the cost for the above mentioned u-track kit is reduced by 40% (that is, € 6 000), then the overall cost for this particular item would be € 73.8 million, as opposed to the € 123 million. The same rationale is valid for costs related to vending machine service vans or mobile sales forces, analysed further below

11.4.2.2.4.2 Vending machine service vans: cost analysis.

Germany was again used as a reference point to calculate the number of vending machine service vans operating in the EU, using the following ratio: ‘average number of vending machines served / average number of vending machines serving vans’. There were 380 000 vending machines in Germany in 2010¹⁴⁰ and considering that there were 1 200 vending machine service vans, the ratio gives us an average number of 316 vending machines served by each service van. This ratio was applied by country and at the EU level resulting in 2,122 vending machines service vans operating in the EU in 2010. Considering that the overall market decreased in 8.4%, as mentioned above, the estimated number of vending machines service vans operating in the EU is estimated to be 1 944 in 2013 (see Annexure 10). Once the number of service vans was estimated, our analysis identified which costs impact the P&L, as shown in Figure 86 below:

	Service vans
I.- Server and software	✓
II.- Utrack kit (PC 2 scanners)	✓
III.- Additional HR costs	✓
IV.- Software maintenance	✓
V.- Annual depreciation	✓
VI.- Registration costs	✓

Figure 87: Costs Identification for Vending Machines Service Vans

The following unitary costs were considered in the analysis:

- Server and software = € 6 000 (source: industry survey)
- Utrack kit (PC 2 scanners and related software) = € 10 000 (source: industry survey) – only 50% of the total vans will need to buy Utrack kits;
- Additional HR operational costs in warehouses = +40% (source: team estimation, considering bigger amount of data to be recorded);
- Software maintenance costs = 10% over investment realized (source: team estimation);
- Annual depreciation calculated on a 6-year life of the investment realized (source: team estimation); and
- Registration costs = € 3 000 (project team estimated an annual average costs at European Union level based on GS1 the Global language of business data, source: <http://www.gs1.org/>).

The following calculations reflect the impact for the vending machines service vans at the European Union level, and are presented into capital expenditure and operational expenditure, the latter including the annual depreciation effect calculated over the estimated investment figures (see Figures 87 and 88 below):

¹⁴⁰ Matrix insight - Economic analysis of the EU market of tobacco, nicotine and related products, September 2013

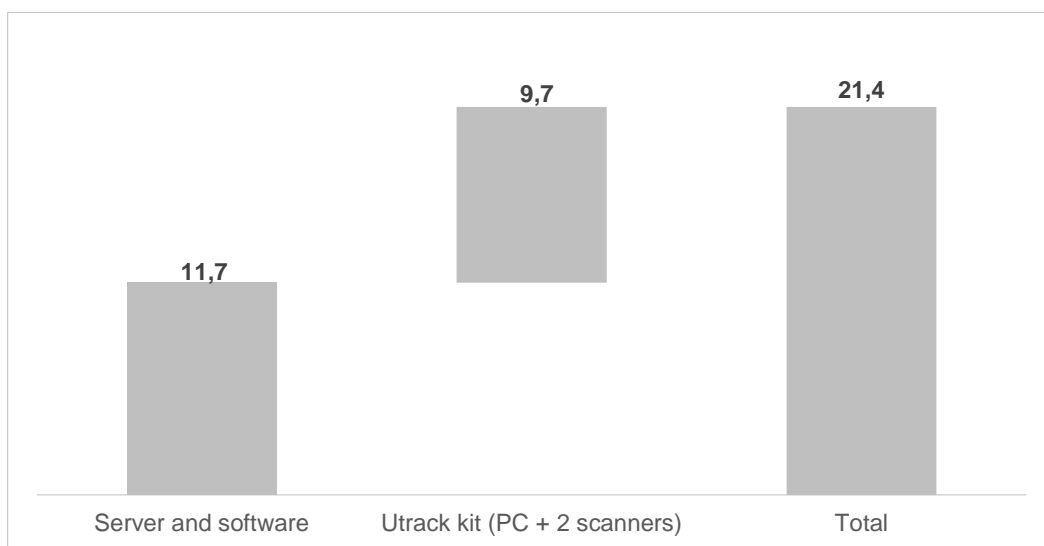


Figure 88– Cost Impacts in Vending Machines Service Vans (CAPEX, in M euros)

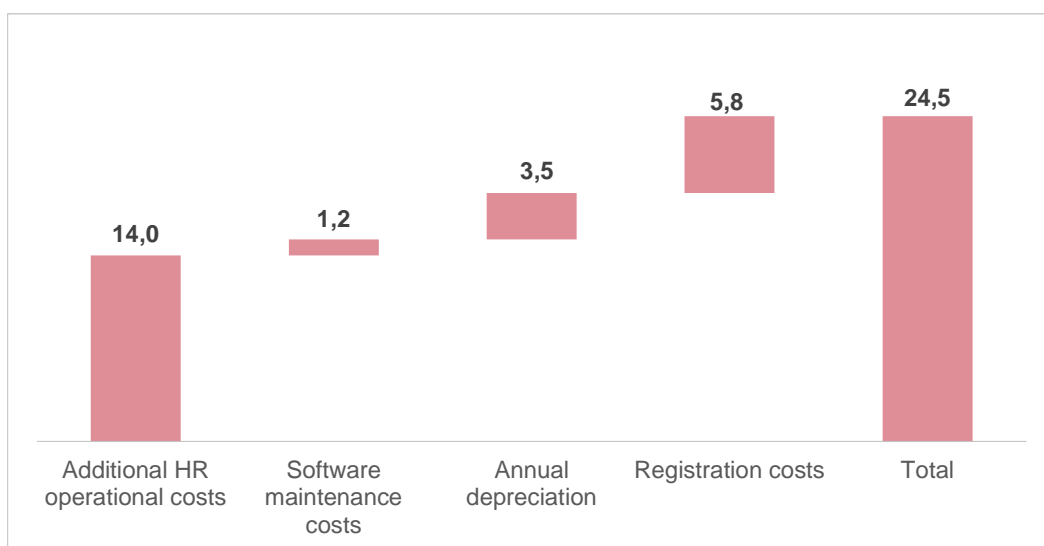


Figure 89– Cost Impacts in Vending Machines Service Vans (OPEX, in M euros)

- Server and software = € 11.7 m (CAPEX).
 - € 6 000 (unitary cost for each server and software pack) x 1 944 (number of service vans in the European Union)
- Utrack kit (PC 2 scanners and related software) = € 9.7 m (CAPEX), to be realized each 6 years.
 - 1 944 (number of service vans) x 50% (of service vans that will need to buy new equipment) x 10 000 euros (unitary cost for each Utrack kit)
- Additional HR operational costs in service vans = € 14.0 m (see Annexure 10).
 - Number of vans (per country) x Average one people doing shipping operation on each van x Minimum wages in the EU (per Member State) x Considering 14 wages per year x 20% incremental operational HR costs
- Software maintenance costs = € 1.2 m (OPEX).
 - 10% (annual maintenance costs) x € 11.7 m (server and software costs)

- Annual depreciation = € 3.5 m (OPEX).
 - € 21.4 m (investment in Utrack kits, server and software) / 6 years life time on investment realized
- Registration costs = € 5.8 m (OPEX).
 - 1 944 (number of vending machines service vans in the EU in 2013) x € 3 000 (average annual registration costs)

11.4.2.2.4.3 *Mobile sales force*

The analysis considered the mobile sales force of all auto sales trucks (individual travelling sales representatives) that supply hotels, restaurants, bars, newsagents, tobacconists and kiosks that are independent from big wholesalers and distributors.

To calculate the total number of the mobile sales force, the same ratio calculated for the vending machine service vans was used. If 1 944 vending machines service vans supplied 50 bn sticks in 2013, this means that each van supplied 25.7 m sticks in 2013 (about € 1.3 m packs). Considering that the mobile sales force supplied 103 bn sticks in 2013²³ that means 3,669 delivering units operated in the EU.

Once the number of mobile sales force was estimated, costs impacting the P&L were identified (see detail in Figure 89):

	MSF
I.- Server and software	✓
II.- Utrack kit (PC 2 scanners)	✓
III.- Additional HR costs	✓
IV.- Software maintenance	✓
V.- Annual depreciation	✓
VI.- Registration costs	✓

Figure 90: Costs Identification for Mobile Sales Forces

The following unitary costs were considered in the analysis:

- Server and software = € 6 000 (source: industry survey);
- Utrack kit (PC 2 scanners and related software) = € 10 000 (source: industry survey) – only 50% of the total vans will need to buy Utrack kits;
- Additional HR operational costs in warehouses = +40% (source: team estimation, considering bigger amount of data to be recorded);
- Software maintenance costs = 10% over investment realized (source: team estimation);
- Annual depreciation calculated on a 6-year life of the investment realized (source: team estimation); and
- Registration costs = € 3 000 (project team estimated an annual average costs at European Union level based on GS1 the Global language of business data, source: <http://www.gs1.org/>).

The following calculations reflect the impact for the mobile sales force at the European Union level, and are presented into capital expenditure and operational expenditure, the

²³ Matrix insight - Economic analysis of the EU market of tobacco, nicotine and related products, September 2013

latter including the annual depreciation effect calculated over the estimated investment figures (see Figures 90 and 91 below):

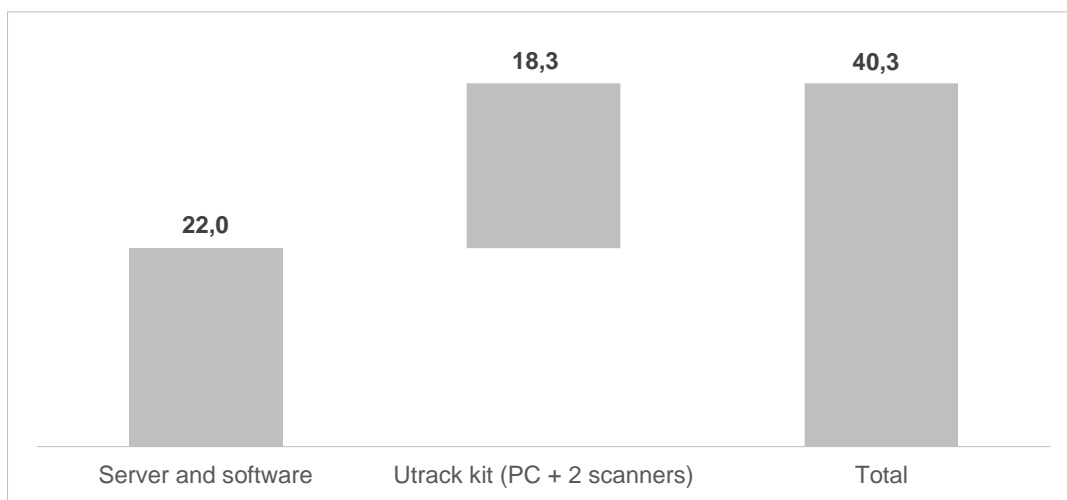


Figure 91– Cost Impacts in Mobile Sales Forces (CAPEX, in M euros)

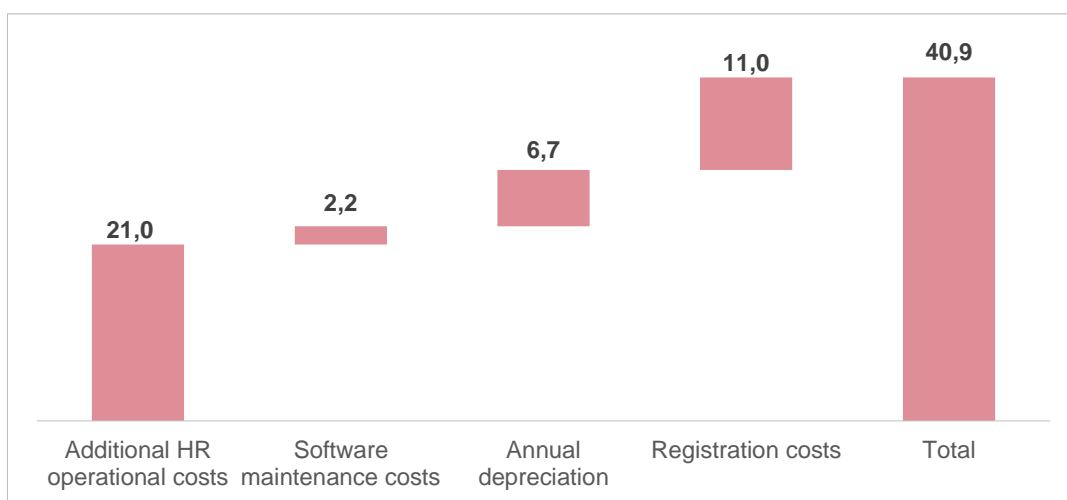


Figure 92– Cost Impacts in Mobile Sales Forces (OPEX, in M euros)

- Server and software = € 22.0 m (CAPEX), one-off costs.
 - € 6 000 (unitary cost for each server and software pack) x 3,669 MSF units
- Utrack kit (PC 2 scanners and related software) = € 18.3 m (CAPEX), to be realized each 6 years.
 - 3,699 (MFS units) x 50% (of MFS units that will need to buy new equipment) x € 10 000 (unitary cost for each Utrack kit)
- Additional HR operational costs = € 21.0 m (see Annexure 10).
 - Number of MFS units (by country) x Average one people doing shipping operation on each MFS unit x Minimum wages in the EU (by Member State) x Considering 14 wages per year x 20% incremental operational HR costs

- Software maintenance costs = € 2.2 m (OPEX).
 - 10% (annual maintenance costs) x 22.0 M euros (server and software costs)
- Annual depreciation = € 6.7 m (OPEX).
 - € 40.4 m (investment in Utrack kits, servers and software) / 6 years life time on investment realized
- Registration costs = € 11.0 m (OPEX).
 - 3,669 (number of mobile sales forces units in the EU in 2013) x € 3 000 (average annual registration costs)

11.4.2.2.5 MEMBER STATES AUTHORITIES

The analysis intends to assess the economic impact of the four proposed traceability solution options on Member States, and for this purpose, two types of costs are considered:

- Implementation costs for a Traceability Information System
 - IT system development
 - IT system maintenance
- Incremental personnel costs for additional staff in law enforcement or similar roles, required to supervise the operation of the traceability solution and market surveillance to ensure only compliant tobacco products enter the internal market.

11.4.2.2.5.1 IT system development and maintenance costs

When assessing costs for developing and running/maintaining an IT software solution that copes with the TPD defined objectives, a set of initial disclaimers should be made:

- No decision has been made by the European Commission as to which solution option (or combinations or variations therefore) fits best the solution requirements;
- A detailed requirement specifications document is not available at present (or in the immediate future);
- Consequently, no investigation was made by the project team in search of “off-the-shelf”, package-based, solutions in the market;
- Some difficulties identifying costs (licensing, acquisition and implementation costs) and potential providers of such solutions given the high degree of unknown circumstances.

In light of the above statements, but considering the need to help the different stakeholders to understand the range of investments they will have to incur, assumptions were made that have used former experience of some of the project team members in IT system development and maintenance effort estimation; additionally, we are assuming that a “systems integrator” would undertake development work, so an average daily rate, as charged by such companies, is used for valuation of the effort. Despite all efforts to prepare a reasonable figure for each of the options, the numbers presented should therefore be considered no more than best estimates.

All figures presented below apply to a single Member State, with the rationale taking into account not only the above considerations but also the fact that EU country specific requirements are unknown, requiring that the project team estimate costs in the calculation for a base application that complies with TPD’s requirements, regardless of what may currently exist in the EU countries. Furthermore, introducing a factor in the

calculations to multiple the value by 28 to account for each Member State would not be reasonable, given that rates for system integrators significantly vary from country to country.

Potential capital costs (e.g., hardware investments) were not considered in the analysis, again for the main reason that no assessment was made to what IT infra-structure exist in the countries, and that budgetary constraints could influence the likelihood of incurring such costs.

In the same way that CAPEX for manufacturers was assessed, cost estimates were first obtained for the existing industry-provided solution (Option 1), and then variations to this rationalised for the remaining Options (2, 3 and 4). The project team considers the following to be the five critical system development stages:

- Project preparation – the initial stage of any system development, consisting of preparing and approving the project charter, including detailed planning of the different stages of the project.
- Detailed requirements definition – identification of the functional requirements the system will have to meet, taking into consideration the objectives of the TPD and the views of different stakeholders. It will serve as the basis for system design (development and customization).
- Development/customization – the stage where the application is built, end-to-end. Including coding, prototyping, unit testing, interface development, data migration and integration testing, this is normally the most time consuming phase of any system development.
- Acceptance – the stage where acceptance criteria is defined and the system as a whole is finally accepted by the different user communities, demonstrating its readiness for day-to-day usage. Training activities are normally taking place during this stage of the project.
- Go-live – the period after which all existing systems (if any) are turned-off and the new one comes into operation, including making adjustments to correct any coding errors or user mistakes.

When assessing the effort that will be needed for developing the system, we have only taken into account the time and costs associated with the team that will be directly responsible for such development, that is, no contribution from other stakeholders (e.g. indirect costs of EU and Member States specialists and stakeholders involved in work sessions regarding requirements identification and validation, participation in testing and training) was included, because it requires a certain level of granularity of analysis and there is no data available for the purpose. All calculations were made for effective time, not elapsed time, to be spent on each of those five phases.

The following rationale was used to determine the numbers in the estimation chart below (see Figure 92):

- Project preparation – it will take approximately three weeks to create a detailed work plan, taking into consideration that the majority of the intended outcomes of the system, as well as the user community, are already known. Based on the team's experience, a small focussed team can be effective in completing a work plan in this time period. Three people will be needed to oversee project management and serve as liaisons to the development team. Keeping the team small will combat the co-ordination and consultation overhead associated with a large team. The project team will have the opportunity to consult with other parties as needed.
- Creating a detailed definition of requirements – as this is a very important step in the overall project, the team allocated six people over the time period of two months to complete. The team will need to meet with and collect in depth

information from all of the different community users, e.g., health, tax (excise), customs and enforcement authorities. This will entail gathering information, carrying out discussions, validating information and gaining approval of requirements for the system.

- Development/customization – our experience shows that the development/customization work normally takes more than double the time it takes to specify the requirements. To be conservative, we have assumed it will take three times longer, which means we are looking at it taking approximately 30 weeks with a team of 10 people developing, customizing, doing interface design and building and testing.
- Acceptance – the process of acceptance should involve the same number of people that participated in the requirements definition stage, but for a longer period of time. Even if knowing that testing should have been done in the previous stage – and ideally all “bugs” and non-conformities were corrected – a buy-in process of the user community is vital to the success of the operation. We have allowed double the preparation time, meaning 6 weeks for the system to be accepted, with training activities included in this time.
- Go-live – the first three weeks after operating the system for the first time is a period where part of the team should be available for helping the user community to run/operate the application and help them gain enough confidence in understanding the system’s needs. It is anticipated that the same number of Full Time Equivalent (FTE) resources would participate in that final stage of system usage.

Phases (Main activities)	Effort estimation for option 1 (Base option)		
	Duration (Weeks)	FTE	Total effort (Days)
1. Preparation	3	3	45
1.1. Develop and approve project charter			
1.2. Prepare and approve detailed plan			
2. Detailed requirements definition	10	6	300
2.1. Manage requirements gathering			
2.2. Validate requirements			
2.3. Finalize scope			
3. Development/customization	30	10	1,500
3.1. Design and configure			
3.2. Unit testing			
3.3. Interface design			
3.4. Integration testing			
4. Acceptance	6	6	180
4.1. Prepare and approve acceptance criteria			
4.2. Confirm acceptance			
5. Go-live	3	6	90
	52	31	2,115

Figure 93- IT system development effort estimation (Option 1)

In terms of valuating this effort, since the consulting markets vary a lot between Member States, we have used two daily consulting fee rates (€ 700 and € 1 200 for scenarios 1 and 2, respectively) and calculate investment (CAPEX) accordingly. This exercise does not take into consideration any synergies that may occur where development efforts are shared across multiple Member States, where savings on efforts and costs should be expected. The annual depreciation (OPEX) was also calculated, considering a 6-year lifetime of the investment realized.

Regarding maintenance, we use a % of total effort, taking into consideration the commonly charged rates by software developers/integrators; 15% was the selected figure.

<i>Assumptions</i>	Scenario 1	Scenario 2
Cost (€) per day	700 €	1,200 €
Estimated asset lifetime (years)	6	
Maintenance costs (as a % of total development costs)	15%	

Again, these figures should be considered for a single Member State. It should be noted that a competitive bidding process could significantly influence the overall cost of developing and maintaining such a system.

Variances of Options 2, 3 and 4 vis-à-vis Option 1 are explained by the advantages/disadvantages of each option, as described in section 8 of this report. The following table outlines the most relevant factors considered when coming up with these estimates.

OPTION COMPARISON	VARIANCE EXPLANATION
Option 2 vs. Option 1	The experience of the appointed solution provider(s) with experience implementing or using similar types of systems is likely to reduce the time needed to create the detailed requirements definition, under the expectation that several solution components would already exist as a basis for customisation / enhancement. Furthermore, fewer adjustments and interface development/customization should be necessary as a single EU-wide system is provided by the solution provider(s).
Option 3 vs. Option 1	Each Member States developing individual requirements – whether operated by the industry or a solution provider independent from the industry – is likely to result in duplication of effort for similar components, with further additional effort required to reconcile the requirements for integration / interfacing with current/existing systems.
Option 4 vs. Option 1	The involvement of an independent solution provider may introduce some cost saving advantages similar to Option 2 above; however, the potentially larger number of entities involved in the construction of the system adds complexity that may neutralise this advantage. Therefore, for the purposes of the analysis, it has been assumed that overall effort will be the same as Option 3.

Taking into account these considerations, the time and effort comparisons for the development of the required solution between the 4 options are presented in Figure 93 below:

<i>Total Effort (in Days)</i>	Option 1 (Base)	Option 2	Option 3	Option 4
	As % of Option 1			
1. Preparation	45	100%	100%	100%
2. Detailed requirements definition	300	50%	120%	120%
3. Development/customization	1,500	50%	150%	150%
4. Acceptance	180	100%	100%	100%
5. Go-live	90	100%	100%	100%
	2,115	1,215	2,925	2,925

Figure 94: Total Effort comparison between four traceability options

Considering these variances, as well as the different average daily costs for each scenario and the estimation of maintenance costs as a % of total development costs, Figures 94 and 95 below present a cost comparison between the 4 options under two different scenarios:

	T&T Option 1	T&T Option 2	T&T Option 3	T&T Option 4
Development Costs (CAPEX)	1,480,500 €	850,500 €	2,047,500 €	2,047,500 €
Annual depreciation	246,750 €	141,750 €	341,250 €	341,250 €
Maintenance Costs (OPEX)	222,075 €	127,575 €	307,125 €	307,125 €
Annualized total costs (OPEX + annual depreciation)	468,825 €	269,325 €	648,375 €	648,375 €

Figure 95– IT system annualized total costs (average daily charge rate = 700 €)

	T&T Option 1	T&T Option 2	T&T Option 3	T&T Option 4
Development Costs (CAPEX)	2,538,000 €	1,458,000 €	3,510,000 €	3,510,000 €
Annual depreciation	423,000 €	243,000 €	585,000 €	585,000 €
Maintenance Costs (OPEX)	380,700 €	218,700 €	526,500 €	526,500 €
Annualized total costs (OPEX + annual depreciation)	803,700 €	461,700 €	1,111,500 €	1,111,500 €

Figure 96– IT system annualized total costs (average daily charge rate = 1,200 €)

Additional to the system development costs detailed above, it is envisaged that a query tool / mechanism would need to be developed for use by EU and Member State authorities to conduct tracing queries using tobacco data from the independent data management provider. As this application would largely be universal across Member States, there would be an efficiency advantage for developing a standard base mobile application and web service for traceability queries (which Member States may then develop further to extend with additional functionality in the future, though considered out of scope for this cost / benefit analysis). It is anticipated that development costs for a mobile application (suitable for smartphone devices), and web portal application would be approximately € 70 k – € 90 k).

An additional cost component related to server hosting services is also to be considered for each of the four proposed options. In accordance with pricing data obtained from Amazon regarding Amazon Elastic Compute Cloud (EC2) on Windows with SQL Server, these annual costs (based on prices for Ireland region) will vary from approximately € 20 k to € 70 k, as the next figure shows (see Figure 96):

<i>Instance type</i>	On-Demand Price (per hour)	Option 1	Option 2	Option 3	Option 4
i2.2xlarge	1.98 €	17,338 €			
i2.4xlarge	3.96 €			34,676 €	34,676 €
i2.8xlarge	7.92 €		69,353 €		

Amazon EC2 (Windows with SQL Standard): Storage Optimized - Current Generation

Figure 97– Server Hosting Costs (based on Amazon EC2 pricing)

For reference, *i2.2xlarge* are high storage instances that provide very fast SSD-backed instance storage optimized for very high random input/output, and provide high input/output operations per second at low costs.

These quotations and cost estimations are indicative, and were made based on the assumption that the physical location of servers would be in Ireland, thus complying with Article 15.8 of the TPD.

The possibility also exists of setting-up a Virtual Private Cloud, providing further reliability and access restrictions, whenever necessary.

11.4.2.2.5.2 Additional labour force requirements for enforcement activities

The impact of implementing a new T&T + S/F solution on Member States' authorities personnel will basically depend on a certain set of circumstances, as follows:

- The solution option that will ultimately be adopted;
- The amount of additional monitoring activities each of them will be required to exercise on the value chain and its operators, so as to get most benefit out of the solution;
- The budgetary constraints each of those Member States may face, currently, or in the future, which will affect their real capacity to exercise those additional monitoring activities.

The information that follows was prepared primarily from the survey responses received from the Member States and follow up phone calls and emails to Member States to gather additional pieces of information on particular sections of the survey (survey sections 5 and 7).

To estimate the likely impact of the implementation of such T&T+S/F solution on the Member States, we have:

- Collected Member States data on tobacco movements (national inter-warehouse, EMCS imports into and EMCS exports from the Member States), in order to gain a perception of the level of "adequacy" of workforce numbers of the major operations in each individual market;
- Used information related to the current workforce roles, determined as far as possible, to be relevant for the operations of a tobacco traceability solution where provided by the Member States in the survey;
- Considered the ability to increase workforce numbers, as declared by Member States;
- Extracted from Eurostat the available figures for average public administration and defence salary and wages in 2012; and
- Used the last three information items to assess the incremental impact on costs for each of the EU-28 countries (where the data was available within Eurostat) and for each of the solutions that have been analysed throughout this report.

As the report clearly suggests, each of the solutions will impact Members States at different levels:

OPTIONS	RATIONALE AND LEVEL OF IMPACT
<p>Option 1</p>	<p>Means that Member States will rely on the tobacco industry as source of tobacco traceability data, requiring supplementary supervision controls to include additional checks and balances for the purposes of validating the integrity of a tobacco products traceability solution – Due to the high dependence on tobacco industry to self-manage data, we have considered this solution to have a "high impact" on labour force requirements for law enforcement agencies;</p>
<p>Option 2</p>	<p>Implies that data of tobacco products traceability solution is created and managed by an independent solution provider, reducing the risk of manipulation. It also entails that data output from this solution could be leveraged by Member State agencies to support current supervision functions and that Member States would be able to conduct regular market surveillance campaigns to verify compliance of EU manufactured tobacco products, assessing levels of illicit items on the internal market. – option to which we have given a "low impact";</p>

OPTIONS	RATIONALE AND LEVEL OF IMPACT
Option 3	The impact of this blended solution may differ if Member States choose to appoint tobacco manufacturers (3A) or an independent solution provider (3B) as source of tobacco traceability data, considering the different risk levels of data manipulation for each choice. However, given this flexibility of each Member States to appoint the operator of the solution, oversight by Member States authorities is mixed, potentially provided by tobacco manufacturers in some Member States, and by an independent solution provider in others. Member States will actively use traceability data for monitoring and control purposes and will audit traceability information to validate integrity of the solution. Due to the partial dependence on tobacco industry for data provision, we have considered this solution to have a “medium impact” on labour force requirements for Member States authorities.
Option 4	Whereas responsibilities of the Member States are similar to those described in Options 2 and 3 above, a “low impact” was attributable to this option, given the reliability of the traceability information provided by an independent solution provider.

The following table summarizes the level of impact being considered for each option:

Option 1	Option 2	Option 3	Option 4
High	Low	Medium	Low
20%	5%	10%	5%

The following figures intend to provide CHAFEA and the Commission with the project team’s estimation for Member States incremental labour associated costs, in recognition that just a limited number of countries have provided us with the relevant data and showed at least some ability to increase workforce numbers for audit and inspection roles.

	Inspection + Audit staff	T&T Option 1	T&T Option 2	T&T Option 3	T&T Option 4
MS “A”	28	75,163 €	18,791 €	37,582 €	18,791 €
MS “B”	65	162,760 €	40,690 €	81,380 €	40,690 €
MS “C”	155	492,528 €	123,132 €	246,264 €	123,132 €
MS “D”	33	314,332 €	78,583 €	157,166 €	78,583 €

Figure 98: MS incremental labour costs for inspection and audit roles

EUROPEAN COMMISSION

<i>Member States</i>	Inspection+ Audit Staff	Average annual Wages and salaries per person (€) ¹	Ability to increase	Option 1	Option 2	Option 3	Option 4
MS #1	272	N/A	Not prov.				
MS #2	Not prov.	5,579	Not prov.				
MS #3	28	13,422	Some	75,163 €	18,791 €	37,582 €	18,791 €
MS #4	0	N/A	RNO				
MS #5	Not prov.	N/A	Not prov.				
MS #6	65	12,520	Some	162,760 €	40,690 €	81,380 €	40,690 €
MS #7	0	N/A	RNO				
MS #8	Not prov.	27,056	Likely				
MS #9	Not prov.	N/A	Not prov.				
MS #10	155	15,888	Some	492,528 €	123,132 €	246,264 €	123,132 €
MS #11	Not prov.	N/A	Not prov.				
MS #12	Not prov.	N/A	Not prov.				
MS #13	50	N/A	None				
MS #14	0	10,262	None				
MS #15	0	9,456	RNO				
MS #16	0	N/A	RNO				
MS #17	Not prov.	11,132	Likely				
MS #18	0	N/A	RNO				
MS #19	33	47,626	Likely	314,332 €	78,583 €	157,166 €	78,583 €
MS #20	0	N/A	RNO				
MS #21	1600*	N/A	Some				
MS #22	15	17,602	None				
MS #23	0	6,264	RNO				
MS #24	Not prov.	25,553	Not prov.				
MS #25	0	10,383	RNO				
MS #26	15	N/A	None				
MS #27	0	N/A	RNO				
MS #28	0	42,092	Not prov.				

¹ Labour cost, wages and salaries, direct remuneration - NACE Rev. 2 (source Eurostat2012), Public Administration and Defence

* As was provided by the MS, validity of the information has to be checked, probably because of an incorrect/incomplete understanding of what was requested.

Figure 99: Incremental labour costs for each option, by Member State

Member States will also be expected to incur the costs related to providing information on the new track and trace system to all stakeholders, stemming from law enforcement agencies, tobacco inspection and audit staff, to the consumers themselves, so as to make them aware of the authenticity features they will be able to check whenever buying a pack of cigarettes or another tobacco product.

Given that scope and extent of any campaigns and informative actions will depend on each individual Member State, the project team has not developed any cost estimation for this purpose.

Nonetheless, it is the project team's firm belief that it is in the Member States' interests to actively pursue monitoring activities, given that it may have an immediate impact on

their fiscal revenues. Furthermore, savings can be achieved in view of potential synergies with other monitoring activities that are already undertaken by Member States.

11.4.3 SECURITY FEATURES COST ANALYSIS

11.4.3.1 METHODOLOGICAL APPROACH

The cost / benefit analysis for security features was based on the cost of the proposed security feature options that were presented in the preliminary analysis, which included:

1. Security feature package similar to using fiscal markings.
2. Security feature package to complement the industry proposed solution.
3. Security feature packaging using emerging covert technology.
4. Security feature package that includes using a unique identifier.

There are two dimensions of the costs to be derived for each package:

- a) The costs of producing the security features; and
- b) The costs of applying such security features to a single production line.

For the first cost dimension, the methodology adopted derived a base scenario that allowed the solution providers to provide a cost range for both 1 and 2 above. This was applied to all eligible survey respondents. Eligible respondents are those that were able to provide both Overt and Covert security features. The base scenario will be based on the estimated total annual production volume for the EU, and provided as the total number of cigarette packs and packs of Other Tobacco Products.

For the second cost dimension, the respondents were not expected to provide a fixed cost per unit of production, but rather a cost range to be based on all hardware, software, operating and related costs to apply the security feature to one of the production lines.

The base scenario would be for these production facilities located in the EU.

The expected response was then:

X Cost to produce Y security features where:

X = total costs to produce security features as described in the security package.

Y = Total annual EU production volume.

11.4.3.2 RATIONAL AND CALCULATIONS

11.4.3.2.1 INDICATIVE VOLUMES CALCULATION: NUMBER OF MARKS TO BE PRODUCED

Whilst in the T&T cost analysis – see page 289 – the contracting team has considered the cigarette market as the most relevant and representative of the overall tobacco business (of which the available information relates to production lines only), here for S/F cost analysis such information is available for the different tobacco categories, as follows:

- **Cigarettes:** according to Euromonitor, there will be 545 bn sticks by 2015 (forecast, about 28 bn cigarette packs assuming an average of 20 sticks per

pack). In addition, marking cartons will mean 2.8 bn additional units (assuming an average of 10 packs per carton).

- **Roll-your-own (RYO):** according to Euromonitor, there will be 74 thousand tonnes in 2015. Assuming mixed pouches of 30g (30%), 50g (30%), 100g (30%) and 200g (10%) this means 1 bn units shall be marked.
- **Cigars:** according to Euromonitor, there will be 10.5 bn cigars in 2015. Assuming boxes of 5 units (20%), boxes of 10 units (20%), boxes of 15 units (20%), boxes of 20 units (20%) and boxes of 25 units (20%) this means that 959 m units will have to be marked.
- **Pipe tobacco:** according to Euromonitor, there will be 4 thousand tonnes in 2015. Assuming an average pack of 50g this means about 80 m packs to be marked.
- **Smokeless tobacco – chewing tobacco:** according to Euromonitor, there will be 18 tonnes in 2015. Assuming an average pack of 10g this means about 1.8 m packs to be marked.
- **Smokeless tobacco – snus:** according to Euromonitor, there will be 6 thousand tonnes in 2015. Assuming packs of 20g (40%), packs of 40g (40%) and packs of 60g (20%) this means 160 m packs to be marked.

In total, there will be a need for 33 bn units to be marked with security features altogether.

In the analysis, two different marking solutions were considered: dry label (a label without glue / adhesive on it suitable for application using high speed applicators such as those used on cigarette production lines) or self-adhesive labels (suitable for application using handheld label applicators or even by hand). Depending on the tobacco product nature, it will be marked with one kind of mark or the other, as shown in the Figure 99 below:

	Dry label	On-product marking	
Cigarettes: packs	28 000		M packs
Cigarettes: cartons	2 800		M cartons
Cigars:	671	288	M units
RYO:	1 013		M units
Pipe tobacco:		80	M packs
Smokeless tobacco: chewing tobacco		2	M packs
Smokeless tobacco: snus		160	M packs
	32 484	530	33 Bn

Figure 100: Total Number of Units to be Marked at EU Level, Split by Typology

11.4.3.2.2 SECURITY FEATURES COST CALCULATION.

OPTION 1: SECURITY FEATURE PACKAGE SIMILAR TO FISCAL MARKINGS

Indicative price ranges were considered from the survey results received from the industry, giving minimum and maximum price ranges for each marking solution, as shown in Figure 100 below:

	Min	Max	Average	
Dry label – 1.5-3 Euro per 1000 packs	0.0015	0.0030	0.0023	(€ per pack)
Self adhesive – 3-5 Euro per 1000 packs	0.0030	0.0050	0.0040	(€ per pack)

Figure 101: Average Unitary Price for Security Feature Option 1

Assuming the average price for each of the marking solutions presented and multiplying that by the number of units to be marked in the EU, we conclude that the total cost of this solution for all the Member States is € 75.2 m, as shown in Figure 101 below:

(in euros)	Dry label	Self-adhesive	TOTAL
Option 1 total cost	73,089,675	2,118,000	75,207,675

Figure 102: Security Feature Option 1 Total Cost Calculation

Unitary costs for the security features Option 1 are equal to € 0.0023 / unit marked.

OPTION 2: SECURITY FEATURE PACKAGE TO COMPLEMENT INDUSTRY PROPOSED SOLUTION

Due to the semi-covert elements that are not needed in Option 2, instead fulfilled by the argument that the unique identifier could be used to provide traceability verification, there was a 15% cost reduction versus Option 1.

Considering a 15% reduction in costs versus Option 1, this gives us a total cost for Option 2 of € 63.9 m (€ 0.0019 / unit marked).

OPTION 3: SECURITY FEATURE PACKAGING USING EMERGING COVERT TECHNOLOGY

Option 3 presents the same characteristics as Option 2, as fingerprinting also provides the covert and semi-covert features. In addition to costs calculated in Option 2, there were additional costs considered:

- Camera systems to be installed on every production line (CAPEX): assuming unitary costs of € 45 k, this gives an additional cost of € 33.6 m (assuming 743 production lines in the EU).
- Annual depreciation was calculated over these investments (OPEX) considering 6 years life of the investment realized, which gives an annual depreciation equal to € 5.6 m.
- An additional fee to be paid per pack fingerprinted (OPEX) of € 75 per 100 000 units marked: assuming 32 bn packs this gives additional costs of € 24 m.

Considering annualized total costs (OPEX + depreciation), Option 3 equals € 94.3 m (€ 0.0029 / unit marked).

OPTION 4: SECURITY FEATURE PACKAGE INCLUDING UNIQUE IDENTIFIER

In order to calculate the total costs for Option 4, indicative price ranges were considered from the survey results received from the industry, giving minimum and maximum price ranges for each marking solution, as shown in Figure 102 below:

	Min	Max	Average	
Dry label – 1.5-3 Euro per 1000 packs	0.0035	0.0050	0.0043	(€ per pack)
Self adhesive – 3-5 Euro per 1000 packs	0.0050	0.0070	0.0060	(€ per pack)

Figure 103: Average Unitary Price for Security Feature Option 4

The total cost for security features Option 4 are € 141.2 m (€ 0.0043 / unit marked). See detail in Figure 103 below:

(in euros)	Dry label	Self-adhesive	TOTAL
Option 4 total cost	138,058,275	3,177,000	141,235,275

Figure 104: Security Feature Option 4 Total Cost Calculations

12 CONCLUSION

This Final Report includes Tasks 1 through 6 of the Tender requirement document. In compiling this report, the project team completed the following:

- Developed a problem statement and provided the context of the traceability and security feature requirements and developed several solution critical success factors for each **(Section 2)**.
- Provided an overview of the principles of Traceability and Authentication, including a brief benchmark against other industries and a review of emerging standards **(Section 4)**.
- Conducted a review of tobacco traceability solutions in operation **(Section 5)**.
- Developed a methodology and presented an overview of the current landscape of traceability solution providers and security feature providers **(Section 6 & 7)**.
- Performed a feasibility study from the perspective of the stakeholders of the four traceability solution options **(Section 8)** and similarly for the security feature options **(Section 9)**. This study included, per solution:
 - Key implications and requirements,
 - Advantages and disadvantages,
 - Legal compatibility of the solution with the TPD,
 - Compatibility with the critical success factors described as part of the problem statement.
- Provided the details for a data storage contract **(Section 10)** in terms of size, location and administrative and maintenance requirements.
- Conducted a cost benefit analysis of the traceability solution and security feature solution options **(Section 11)** by establishing a model of baseline costs for the various stakeholders. This model has the flexibility to be considered with different input criteria and from different perspectives (supply chain perspective, Member State perspective, etc.).

The cost/benefit analysis conducted for this report clearly shows that no matter which traceability and security feature option is selected, the benefits outweigh the costs from both economic and social perspectives. The four track and trace options outlined in this report provide a mechanism to distil out multiple options, decision points and performance criteria for future consideration and action. Additional analysis and decisions will be required in a number of areas in order for the Commission to be in a position to commence with the implementation of a solution. This would include, inter alia, agreement on a governance model for the system (e.g., Member State or Commission level), development of system user requirements, vulnerability assessment of solution options and deciding on a final system architecture and security feature package.

13 KEY CONSIDERATIONS

In addition to the information included in the above sections, the project team would like to additionally outline some key points for CHAFEA and the European Commission to consider regarding implementing a track and trace and security feature solution.

13.1 TRACEABILITY AND SECURITY FEATURES CONSIDERATIONS

In an effort to supplement the feasibility study, several key considerations were identified. Specifically for traceability, these key considerations were:

Additional Considerations for Traceability Solutions		
Section	Heading	High Level Recommendations
8.6.1	EU Standards For The Size And Location On Tobacco Product	It is recommended that EU standards allow flexibility in the choice of location for the unique identifier on the tobacco product.
8.6.2	Data Elements Forming Part Of The Unique Identifier	Specific recommendations are made on the unique identifier in terms of combining similar elements, utilising the barcode and increasing the scope of linked data.
8.6.3	Security and Encryption of the Unique Identifiers	Encryption of the unique identifier at the time of application may provide an additional security advantage in the context of a traceability system, and asymmetric encryption provides a mechanism to segregate keys used for encryption and keys used for decryption. By storing the unencrypted unique identifier in the traceability data repository, it provides a safeguard should the traceability data be compromised during transmission or at the data storage site. In the event of this, the illicit operators would not be able to generate valid encrypted unique identifiers without further having access to the encryption key.
8.6.4	Consolidating Member State Requirements at Production Source	In the context of traceability option 3 where individual Member States appoint potentially different solution providers, a mechanism to ensure interoperability is recommended to prevent possible duplication of equipment and solutions on a tobacco production line that may be manufacturing tobacco products for multiple EU Member States.
8.6.5	Distribution Chain Readiness	Based on the selected traceability and security feature solution options, it is recommended a readiness survey be conducted of the distribution chain operators to guide the implementation model. A segmented and differentiated implementation approach may be considered for different categories of distribution chain operators (e.g. vending machine operators, cash & carry wholesalers and mobile sales forces).

Additional Considerations for Traceability Solutions

Section	Heading	High Level Recommendations
8.6.6	Regulating compliance in the distribution chain	It is recommended that potential obligations on manufacturers and distribution chain operators to reconcile discrepancies between themselves be considered in developing the legal framework of implementing legislation. Because of the administrative burden this imposes on these operators, it is recommended that this not be implemented at the outset, but rather discrepancies in the distribution chain are monitored, with increasing levels of intervention applied as necessary.
8.6.7	Granularity of recorded traceability events	Recommendation that the traceability solution to require all dispatch and receipt operations by distribution chain operators to be recorded. As a result, business events by transporters and logistic providers would not need to be recorded while goods are in the process of being transported.
8.6.8	Integration with Customs and Excise Systems	<p>Customs: Linkage between the traceability solution and Member State export systems to record exit of tobacco products from EU territory, assist volume reconciliation, support customs risk analysis and provide basis to detect potential diversion of exported goods re-entering the EU market. Traceability solution and security feature could assist Customs officials at frontier validate legitimate tobacco consignments and provide data to support risk management activities.</p> <p>Excise: It is recommended that the European Commission conduct a further assessment of a potential linkage between the EU EMCS solution and proposed tobacco traceability solution to potentially strengthen controls related to tobacco movements under duty suspension. Further, potential data synergies should be further assessed in terms of using traceability data as a reconciliation against excise declarations, as well as revenue forecasting and planning.</p>
8.6.9	Related Commercial Documents Supporting Traceability Events	Article 15 §2(k) of the TPD identifies the requirement for commercial documents and related business event data that will need to be referenced or recorded by the traceability solution. The report identifies three options in which this potentially could be implemented with progressively demanding implications and benefits for different stakeholders. It is recommended that information requirements for these records and data are developed by the Member States and EU Commission, and that if necessary (based on the impact on manufacturers and distribution chain operators), a phased implementation approach be adopted.
8.6.10	Extensions to current standards for traceability information exchange	It is proposed that during subsequent project phases, technical representatives of European Commission directorates (including DG SANCO, DG TAXUD and OLAF) and Member State parties consider participation in the technical forums of GS1 as a mechanism to facilitate implementation of these extensions in a manner acceptable to both industry and government stakeholders
8.6.11	Field Inspection Support	Different degrees of sophistication can be considered in providing an application to support EU and MS authorities in the context of a tobacco traceability solution. Replication of development effort would not be efficient, and an exercise to consolidate user requirements from respective authorities using the traceability solution in each MS, as well as at EU level should be undertaken to develop a consolidated set of user requirements.

Additional Considerations for Traceability Solutions		
Section	Heading	High Level Recommendations
8.6.12	Solution Supervision and Controls	A framework of supervision and control has been recommended to ensure the efficacy of the selected and implemented traceability solution.
8.6.13	Considerations For Small Producers	Its recommended the EU Commission and Member States consider the further option of a blended approach, where perhaps traceability Option 1, 2 or 3 are considered for cigarette and roll-your-own tobacco products, while Option 4 might be recommended for the other tobacco products.

Table 45 - Additional Considerations for Traceability Solutions

The key considerations for security features were (**Section 4.1**):

Additional Considerations for Security Features		
Section	Heading	High Level Recommendations
9.1.2	Establishing Security Requirements Beyond the Security Feature Itself	The following recommendations are provided for consideration in the case of all four security feature options: <ul style="list-style-type: none"> ▪ Whilst Option 4 considers the addition of a unique identifier to the security feature, its recommended that at least basic serialisation of the security feature is considered for the other 3 options as well. This provides the basis for controls and accountability for possession of the security feature elements. ▪ Further, a control system should be in place accordance with security printing standards (such as ISO14298:2013(E) Management of Security Printing Processes, NASPO certification) for risk management and control of the security feature elements.
9.1.3.	Security Feature Rotation and Risk of Counterfeiting	It is recommended that the security feature be reviewed every 3 to 5 years, (minimum every 5 years) to evaluate the security elements used to create the security features.
9.1.4	Safe for Use on Tobacco Products	All materials, including paper, ink, taggants and glues required for implementation need to consider basic health safety.
9.1.5	Economies of Scale Affecting Production	It is envisaged that consolidating production of security features for the collective EU market is unlikely to yield any significant cost advantage over larger Member States sourcing individually. For those EU Member States with lower volume requirements, there may be an incentive to pool security feature sourcing to attain the full economies of scale
9.1.6	Flexibility to accommodate the variety of tobacco packaging	It is recommended that some flexibility for the label application method is allowed to accommodate the varieties of packaging types, and the mix of production processes associated with tobacco products in the EU that spans very high volume automated cigarette pack manufacture through to specialty low volume and hand packaged tobacco items.

Additional Considerations for Security Features		
Section	Heading	High Level Recommendations
9.1.7	Security feature size	It is recommended that a mix of security feature sizes be specified for different categories of tobacco products. Where stamps / labels are used for high speed cigarette manufacturing lines, compatibility with existing label applicators size requirements is anticipated to provide both a reliability and cost advantage.
9.1.8	Security Feature Position On The Tobacco Product	<p>The following considerations relate to the placement of the security feature on the tobacco product units:</p> <ul style="list-style-type: none"> ▪ As indicated in Article 16, the security feature should be irremovable, and therefore applied directly to the tobacco pack, and under any clear wrap materials ▪ Placement under the clear wrap also provides a level of protection to the security feature during transport; ▪ It is recommended that the security feature is placed in such a manner over the tobacco pack opening (for both soft packs and flip-top style packs) ▪ Placing the security feature near the top of the pack where it will not be obscured by retail stands also allows quick visual inspection that displayed stock is compliant.

Table 46 - Additional Considerations for Security Features

13.2 COST BENEFIT ANALYSIS CONSIDERATIONS

As presented in Section 11, the cost / benefit analysis shows that, no matter which solution option is chosen, the benefits outweigh the costs of implementing a track and trace and security features system that complies with Articles 15 and 16 of the Tobacco Products Directive.

The following is a list of points CHAFEA and the European Commission may want to consider in an effort to realize the highest amount of benefit of such a solution while trying to keep the cost/investment low:

- Conduct a current, in-depth analysis of the tobacco illicit trade market that assesses current volumes and trends over the three most recent years and identifies the current types of illicit trade;
- Coordinate joint efforts with other industries that are affected by illicit trade in an effort to learn what types of technical solutions are most effective and the costs of such solutions – looking at those that derive the most advantages on public health and limit the negative consequences in regards to Member State budgets;
- Conduct a competitive bidding process that will hopefully lead to economies of scale and increased “negotiation bargaining power”, for example, if a given architecture and technological solution is used, as opposed to many. In any circumstance, a detailed requirements specification document will have to be created, so that solution providers, system integrators, data storage companies, etc., fully understand the scope of the technical implementation;
- Costs that have been considered within the Cost Benefit Analysis section of the document do not take into consideration the investment that tobacco manufacturers have made so far to ensure traceability, or the on-going depreciation of these existing capital investments. Rather, the project team has developed a customized approach to cost data collection from the industry, to

which security feature cost range figures have been added to. Other value chain operators costs, e.g., wholesalers, vending machines service vans, mobile service forces were determined with the understanding that there is insufficient information about a number of players both at the EU and Member State level. The project team has used conservative figures for analyses.

- In regards to system development and maintenance, specifically database access, query and reporting – because there is not an existing requirement specification and the fact that limited information was received from Member States surveys, the costs in our analysis should be considered as indicative, despite having been drawn from the project team’s experience in the field.

13.3 OTHER CONSIDERATIONS

Further, there are a number of key activities which do not form part of the scope of this report, but are recommended for consideration in the next phase of requirements development and solution design which include:

- Given the considerations of the four solution options in the context of the WHO FCTC Protocol, it is recommended that the EU Commission request a legislative and technical analysis of Option 1 and its compatibility to both the FCTC Protocol and Tobacco Products Directive.
- The future proposed solution design would need to be evaluated against the extent to which it may be susceptible to security attacks. Particularly, hybrid systems which integrate different solutions for different Member States may pose an additive security threat. Therefore, all final system proposals would need to be considered from a threat analysis standpoint (to ensure measures such as encryption, code signing and secure transmission protocols are employed throughout).
- This report does not assess the potential legal liabilities of the respective parties involved in the operation of a required solution (consider legal liability that may cover unplanned stoppages to production, data breaches), and it is recommended that this be included as a key assessment during the subsequent solution design phases.
- Customs organisations could benefit from utilising traceability information as either a third party confirmation of Import of goods entering into the EU or as validation of volumes produced for Export of goods out of the EU. This should be considered further by Member States during the next project stages.

14 DATA USED FOR THE ANALYSIS

- European Commission – Impact Assessment for a Directive of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products.
- Project Sun: A study of the illicit cigarette market in the European Union – KPMG, 2013.
- KPMG EU Flows Model 2007 – 2013.
- KPMG EU Flows Model calculations 2006 – 2013.
- KPMG analysis based on EPS, LDS and ND(L) research.
- EC Excise Duty tables (Part III – Manufactured Tobacco) and manufacturer estimates for non-EU countries.
- European Commission Releases for consumption of fine cut tobacco 2002-2012.
- Eurostat, 'Euro area annual inflation down to 0.7%', November 2013.
- Gross Domestic Product (GDP), Euromonitor.
- GfK Empty Pack Surveys, 2006-2013.
- European citizens' attitudes towards tobacco control policy measures - Special Eurobarometer 385, May 2012.
- S&P Index 500 Stocks margins by sectors - Revenues (sales to tobacco industry or of tobacco products) and profits.
- Company financial reports 2010; Companies Internet websites - Revenues and profits reported by the industry.
- Matrix report 2012; 2011.
- Datosmacro – Minimum wages per European Union country, 2013

15 GLOSSARY

1D Barcode - Graphic representation of a unique code using structured combination of white and black bars. Highly machine-readable (most cases irrespective of orientation) and often combined with a human readable component as a failsafe should the barcode be damaged or result in errors when reading.

2D Barcode - A machine-readable code that allows data to be encoded in a matrix of binary cells compatible with most printing techniques. Increases the amount of embedded data that can be stored as compared to the 1D barcode. 2D barcodes often can employ redundancy techniques where data can still be read where part of the barcode is damaged / destroyed. These barcodes are machine-readable only (human readable codes may be printed alongside or beneath).

3rd Party Storage Providers - Independent organizations that provide data storage and application hosting services.

Aggregation - Allows for the identification of each of the items within a container to be recorded, and associated with a unique identifier that is then assigned to the container.

Alphanumeric Codes - A human readable combination of numbers and digits applied to the packaging. Machine readability can be problematic making this unsuitable for medium-to-high volume scanning / verification applications.

Application Identifier (AI) - used as part of the GS1 standard to identify the data type of field encoded within a data barcode (Variable information, such as a batch number, production date or customer purchase order).

Assessment Matrix - Tool used to evaluate the technology solutions, and provide a mechanism to visually represent the potential "fit for purpose" across two dimensions: Functional Scope & Maturity and Breadth of Experience.

Authentication - Process of determining whether someone or something is, in fact, who or what it is declared to be (the genuine article).

Automated Export System - The objective of the Automated Export System is to ensure that export operations started in one Member State can be finalised in another Member State without re-submission of the same information. This includes the exchange of electronic messages related to the different stages of the operations amongst the various actors (customs, traders and other governmental administrations).

Automated Import System - The objective of the Automated Import System is to ensure that import operations started in one Member State can be completed in another Member State without re-submission of the same information. This includes the exchange of electronic messages related to the different stages of the operations amongst the various actors (customs, traders and other governmental administrations).

Breadth of Experience - Assessment of existing implementations, market credibility and current capability of the offered solution.

Cheap Whites - Cigarette brands, produced in an open manner at well-known locations, which are mainly intended for the illegal market in another country. 'Cheap whites' or cigarettes are produced (often legitimately) in their country of origin at a very low cost and are destined to be illicitly sold in other jurisdictions, but do not respect the legal requirements in the jurisdiction of destination.

Codex Alimentarius Commission - International Commission that develops harmonised international food standards, guidelines and codes of practice to protect the health of the consumers and ensure fair practices in the food trade. The Commission also

promotes coordination of all food standards work undertaken by international governmental and non-governmental organizations.

Consumer - Natural person who is acting for purposes which are outside his or her trade, business, craft or profession.

Counterfeit - to simulate, reproduce or modify a material good or its packaging without authorization.

Covert Authentication - Not instantly recognizable or interpretable by the human senses, but requires authentication tools and/or specialized knowledge to verify their presence and validity.

Cross-Border Distance Sales - Distance sales to consumers where, at the time the consumer orders the product from a retail outlet, the consumer is located in a Member State other than the Member State or the third country where that retail outlet is established.

Data Matrix - Two-dimensional matrix barcode consisting of black and white "cells" or modules arranged in either a square or rectangular pattern. The information to be encoded can be text or numeric data.

Data Repository - Database used to store all traceability events and related data related to a tobacco item.

Digital Coding and Tracking Association (DCTA) - an association that represents manufacturers of tobacco products. The mission of the organisation is cited as promoting digital solutions and technical standards to secure supply chains for excisable fast moving consumer goods, such as tobacco and alcohol. Members companies include British American Tobacco, Imperial Tobacco Group, Japan Tobacco International and Philip Morris International. Website: <http://www.dcta-global.com>

Digital Mass Encryption - Generates codes by employing a cryptographic algorithm that generates the codes and eliminates the dependency on a database.

Digital Mass Serialization - Generation of a random or pseudo random code, or number, which is unique for each product.

Direct Marking - Method of applying codes and barcodes directly to product.

Discovery Service - An information systems application operating in an environment of multiple data repositories. The discovery service provides a single point of contact for applications to submit traceability events and updates that are then routed to the relevant data repository based on predefined

Distribution chain - Chain of individuals and organizations involved in getting a product or service from the producer to the consumer.

Distributor/Agent - Major wholesaling companies have local agents (normally small businesses) that sell and deliver tobacco products to retail shops

Electronic Data Interchange (EDI) - Structured transmission of data between organizations by electronic means. It is used to transfer electronic documents or business data from one computer system to another computer system, i.e. from one trading partner to another trading partner without human intervention.

Electronic Product Code (EPC) - Globally unique serial number that identifies an item in the supply chain.

Electronic Product Code Information Service (EPCIS) - Technical product code standard promoted by GS1 (formerly EPCglobal).

Enterprise Resource Planning (ERP) - Ability to deliver an integrated suite of business applications. ERP tools share a common process and data model, covering

broad and deep operational end-to-end processes, such as those found in finance, HR, distribution, manufacturing, service and the supply chain.

Enterprise Service Bus (ESB) - Software architecture model used for designing and implementing communication between mutually interacting software applications in a service-oriented architecture (SOA).

EPCglobal – Part of GS1 since 2011, provides a data model for product movement events of uniquely identified objects in general. Whilst originally developed for the RFID industry, this data model has become a standard for recording supply chain events. These standards and EPCglobal-certified event repositories allow interoperability between systems sharing track and trace information. It should be noted that GS1 EPCglobal has a separate board of governors from the GS1 Management Board. All standard development and maintenance activities that used to be managed by EPCglobal were transferred to the Global Standard Management Process (GSMP) governed by GS1

ePedigree – (sometimes referred to as electronic pedigree) is an electronic document which provides data on the history of a particular batch of a drug. It satisfies the requirement for a 'drug pedigree' while using a convenient electronic form.

European Article Number (EAN) - 13-digit barcode standard. The standard has been renamed International Article Number, but has retained the abbreviation EAN. The EAN-13 barcodes are used worldwide for marking products often sold at retail point of sale.

European Interoperability Strategy (EIS) - Programme of the European Commission; created to develop a joint vision on interoperability architecture. Any technical solution proposed for tracking and tracing systems implemented in the EU should meet the architecture guidelines proposed by EIS for domains where Member States share a common interest.

Excise Movement and Control SEED Number - SEED is a key component within EMCS and is the system used to record details of excise traders who are approved to hold, move or receive goods under excise duty suspension. Each time a new trader's approval is added to SEED, a unique 13 digit reference number is allocated called the 'Excise ID' or 'Excise Registration Number'. The Excise ID is recorded on the excise trader's approval certificate and this enables each excise trader to be uniquely identified.

Excise Movement and Control System (EMCS) - The computerisation and mutual exchange of information concerning movements of excisable goods under duty suspension between the actors involved in these movements. EMCS is used to monitor bulk movements under excise duty suspension (at the truck, container, pallet level and so on).

Excise Tax Stamps – Stamps or labels placed on individual products to indicate that relevant excise duties have been paid.

Forensic Security Feature – Feature identified through laboratory analysis and provide proof of authenticity that can be used for evidence submission in a court of law.

Functional Scope & Maturity - The completeness of the proposed solution offering, are all of the essential elements of a track and trace solution incorporated, demonstrated understanding of industry principles, and a relevant solution offering in terms of the problem statement.

Global Company Prefix (GCP) – Prefix assigned by GS1 that enable companies and organisations to assign globally unique identifiers to their products, assets, documents, locations, logistic units, returnable containers, etc.

Global Location Number (GLN) - Numeric code that identifies organisation or physical entity.

Global Trade Identification Number (GTIN) - Globally unique number used to identify trade items, products, or services. Each organisation registered with GS1 is assigned a globally unique company prefix, providing a range of numbers that can be assigned by the company to each product (or stock keeping unit [SKU])

GS1 - Organization that has the most widely used global standards to improve the efficiency of supply chains globally across sectors. This includes standards for barcodes, data-matrices and unique product identifiers.

Import of tobacco or related products means the entry into the territory of the Union of such products unless the products are placed under a customs suspensive procedure or arrangement upon their entry into the Union, as well as their release from a customs suspensive procedure or arrangement;

Importer of tobacco or related products means the owner of, or a person having the right of disposal over tobacco or related products that have been brought into the territory of the Union;

International Standards Organization (ISO) - an independent, non-governmental membership organization and the world's largest developer of voluntary International Standards.

Japanese Article Number (JAN) - Barcode standard compatible with the International Article Number scheme. Use of the JAN standard began in 1978.

Key Performance Indicator (KPI) refers to a set of quantifiable measures that an organisation uses to gauge or compare performance in terms of meeting strategic and operational goals.

Last Economic Operator - Last commercial entity to be in contact with a product before it goes to the retail outlet.

Manufacturer - Any natural or legal person who manufactures a product or has a product designed or manufactured, and markets that product under their name or trademark.

Manufacturing Execution Systems (MES) - Computerized systems used in manufacturing. MES can provide the right information at the right time and show the manufacturing decision maker "how the current conditions on the plant floor can be optimized to improve production output."

Master Data Management (MDM) - Technology-enabled discipline in which business and IT work together to ensure the uniformity, accuracy, stewardship, semantic consistency and accountability of the enterprise's official shared master data assets.

Mastercases - a shipping unit of tobacco products, usually containing 25 or 50 cartons of cigarettes

mpXML- Standard initiated in 2001 by the meat and poultry industry as a response to the growing economic pressure for exchanging electronic information along the supply chain.

OASIS - Organization that develops and promotes a number of open standards relating to inter-system messaging and system security. In the context of a track and trace system, supports for open standards increases the interoperability with other systems and is essential in a domain where system integration with public and private information systems is critical.

Optical Variable Device (OVD) is a security element that exhibits various optical effects such as movement, hidden images or colour change effects. These properties mean OVDs cannot be photocopied or scanned, and employed to resist replication.

Other Tobacco Products (OTP) refers to tobacco products other than cigarettes including cigars, smokeless tobacco and roll-your-own tobacco.

Outside Packaging means any packaging in which tobacco or related products are placed on the market and which includes a unit packet or an aggregation of unit packets; transparent wrappers are not regarded as outside packaging.

Overt Authentication - Authentication element which is detectable and verifiable by one or more of the human senses without resource to a tool (other than everyday tools which correct imperfect human senses, such as spectacles or hearing aids).

Overt Security Features – Features that can be verified by naked eye, such as colour changing inks, holograms, latent images, watermarks and security threads.

Placing on the market means to make products, irrespective of their place of manufacture, available to consumers located in the Union, with or without payment, including by means of distance sale; in the case of cross-border distance sales the product is deemed to be placed on the market in the Member State where the consumer is located;

Processor / Grower - Individuals and/or companies that either farm, trade leaf and process tobacco, for use by the industry.

Product Serialization (or mass serialization) is the process used by manufacturers to assign and mark each of their products with a unique identifier.

QR Codes - Machine-readable code consisting of an array of black and white squares, typically used for storing URLs or other information for reading by the camera on a smartphone.

Rating: Evaluation or assessment of something, in terms of quality or quantity or some combination of both.

Relational Database Management System (RDBMS) - Database management system that is based on the relational model as invented by E. F. Codd, of IBM's San Jose Research Laboratory.

Retail Outlet - Outlet where tobacco products are placed on the market including by a natural person.

RFID and NFC Tags - Machine-readable tags use radio waves to communicate with a reading device. The tags contain an electronic chip that can store electronic data. The radio waves emitted by the tag-reading device powers the chip, allowing data to be transmitted wirelessly, even where there is no line-of-sight (with some restrictions) Radio Frequency Identification (RFID) has become more pervasive & allows 1-way communication of data from multiple tags to a single reader up to a 1m distance. Near Field Communication (NFC) is a new variation of RFID that allows 2-way communication between the reader and a single tag, but only up to (10cm). Pricing has become more competitive, but remains relatively high compared to other marking methods.

Secure Mark – Text or symbology (e.g. data matrix) that uniquely identifies a product item that is applied to the product using a security feature / security printing technique with the intention of preventing unauthorised parties from applying or manipulating the text or symbology, or replicating the secure mark onto other items.

Security Layering - Combining multiple security features and dramatically increasing the challenge to potential counterfeiters and illicit traders.

Semi-Overt Security Features – Security features requiring a simple tool and minimal training to authenticate the security element.

Serial Shipping Container Code (SSCC) - Number used for the unique identification of logistic units (such as cartons or pallets)

Serialisation – ensuring each and every item is marked with a unique identifier. This provides the basis to monitor and record the existence, location, and associated events of that item from the moment the mark is applied, potentially through its use / consumption lifecycle.

Service Level Agreements (SLA) are part of a contract where a service is formally defined. Particular aspects of an acceptable minimum service - scope, quality and responsibilities - are agreed between the service provider and the service user (e.g. a response to a logged helpdesk request will be provided within 4 hours).

Single Point of Failure (SPOF) - Part of a system that, if it fails, will stop the entire system from working. They are undesirable in any system with a goal of high availability or reliability, be it a business practice, software application, or other industrial system.

Stock Keeping Unit (SKU) – An organisation assigned product identification code that uniquely identifies a product or bundle of products that helps the item to be tracked for inventory and commercial events.

Structured Query Language (SQL) - Special-purpose programming language designed for managing data held in a relational database management system (RDBMS), or for stream processing in a relational data stream management system (RDSMS).

Supply Chain Management (SCM) - Streamlining of a business' supply-side activities to maximize customer value and to gain a competitive advantage in the marketplace.

Tamper Proof/Physical Security Feature - Features, including techniques to provide tamper evidence and elements to prevent transfer and reuse.

Tiered Storage - Assigns different categories of data to different types of storage media in order to reduce total storage cost. Categories may be based on levels of protection needed, performance requirements, frequency of use, and other considerations

Traceability - Ability to track a product or component forward through specified stages of the supply chain to the user, and trace back the history, application or location of that product or component”.

Tracing - Ability to identify the past or current location of an item. Where an item is intercepted, tracing allows the verification of the products route back to its origin, and allows the retrieval of a specific product's time and location history.

Tracking - Concept of marking products with a unique identifier so they can be monitored from the point of production up to the point of sale to the customer, including each step of the process, creating a time and location history for every step.

Unique Device Identification (UDI) System - Intended to assign a unique identifier to medical devices within the United States. It was signed into law on September 27, 2007, as part of the Food and Drug Administration Amendments Act of 2007.

Unique Identifier - Identifier which is guaranteed to be unique among all identifiers used for those objects and for a specific purpose. There are three main types of unique identifiers, each corresponding to a different generation strategy, such as a serial number or a random number

Unit Packet - Smallest individual packaging of a tobacco or related product that is placed on the market.

Universal Product Code (UPC) - Barcode symbology (i.e., a specific type of barcode) that is widely used in the United States, Canada, the United Kingdom, Australia, New Zealand and in other countries for tracking trade items in stores. Its most common form, the UPC-A, consists of 12 numerical digits, which are uniquely assigned to each trade item.

VAT Information Exchange System (VIES) - Electronic means of transmitting information relating to VAT-registration (= validity of VAT-numbers) of companies registered in the EU.

Weighting - Statistical technique in which a data item is emphasized more than other data items comprising a group or summary. A number (weight) is assigned to each data item that reflects its relative importance based on the objective of the data collection.

Wholesaler - Entities that mass distribute tobacco, be it to their distributors/agents or to retail outlets directly.

ANNEXURES

ANNEXURE 1: ARTICLE 8 OF THE WHO FCTC PROTOCOL TO ELIMINATE THE ILLICIT TRADE IN TOBACCO PRODUCTS

"1. For the purposes of further securing the supply chain and to assist in the investigation of illicit trade in tobacco products, the Parties agree to establish within five years of entry into force of this Protocol a global tracking and tracing regime, comprising national and/or regional tracking and tracing systems and a global information-sharing focal point located at the Convention Secretariat of the WHO Framework Convention on Tobacco Control and accessible to all Parties, enabling Parties to make enquiries and receive relevant information.

2. Each Party shall establish, in accordance with this Article, a tracking and tracing system, controlled by the Party for all tobacco products that are manufactured in or imported onto its territory taking into account their own national or regional specific needs and available best practice.

3. With a view to enabling effective tracking and tracing, each Party shall require that unique, secure and non-removable identification markings (hereafter called unique identification markings), such as codes or stamps, are affixed to or form part of all unit packets and packages and any outside packaging of cigarettes within a period of five years and other tobacco products within a period of ten years of entry into force of this Protocol for that Party.

4.1 Each Party shall, for purposes of paragraph 3, as part of the global tracking and tracing regime, require that the following information be available, either directly or accessible by means of a link, to assist Parties in determining the origin of tobacco products, the point of diversion where applicable, and to monitor and control the movement of tobacco products and their legal status:

- (a) date and location of manufacture;
- (b) manufacturing facility;
- (c) machine used to manufacture tobacco products;
- (d) production shift or time of manufacture;
- (e) the name, invoice, order number and payment records of the first customer who is not affiliated with the manufacturer;
- (f) the intended market of retail sale;
- (g) product description;
- (h) any warehousing and shipping;
- (i) the identity of any known subsequent purchaser; and
- (j) the intended shipment route, the shipment date, shipment destination, point of departure and consignee.

4.2. The information in subparagraphs (a), (b), (g) and where available (f), shall form part of the unique identification markings.

4.3. Where the information in subparagraph (f) is not available at the time of marking, Parties shall require the inclusion of such information in accordance with Article 15.2(a) of the WHO Framework Convention on Tobacco Control.

5. Each Party shall require, within the time limits specified in this Article, that the information set out in paragraph 4 is recorded, at the time of production or at the time of first shipment by any manufacturer or at the time of import onto its territory.

6. Each Party shall ensure that the information recorded under paragraph 5 is accessible by that Party by means of a link with the unique identification markings required under paragraphs 3 and 4.

7. Each Party shall ensure that the information recorded in accordance with paragraph 5, as well as the unique identification markings rendering such information accessible in accordance with paragraph 6 shall be included in a format established or authorized by the Party and its competent authorities.

8. Each Party shall ensure that the information recorded under paragraph 5 is accessible to the global information-sharing focal point on request, subject to paragraph 9, through a standard electronic secure interface with its national and/or regional central point. The global information-sharing focal point shall compile a list of the competent authorities of Parties and make the list available to all Parties.

9. Each Party or the competent authority shall:

- (a) have access to the information outlined in paragraph 4 in a timely manner by making a query to the global information-sharing focal point;
- (b) request such information only where it is necessary for the purpose of detection or investigation of illicit trade in tobacco products;
- (c) not unreasonably withhold information;
- (d) answer the information requests in relation to paragraph 4, in accordance with its national law; and the protocol to Eliminate Illicit Trade in Tobacco Products;
- (e) protect and treat as confidential, as mutually agreed, any information that is exchanged.

10. Each Party shall require the further development and expansion of the scope of the applicable tracking and tracing system up to the point that all duties, relevant taxes, and where appropriate, other obligations have been discharged at the point of manufacture, import or release from customs or excise control.

11. Parties shall cooperate with each other and with competent international organizations, as mutually agreed, in sharing and developing best practices for tracking and tracing systems including:

- (a) facilitation of the development, transfer and acquisition of improved tracking and tracing technology, including knowledge, skills, capacity and expertise;
- (b) support for training and capacity-building programmes for Parties

that express such a need; and

- (c) further development of the technology to mark and scan unit packets and packages of tobacco products to make accessible the information listed in paragraph 4.

12. Obligations assigned to a Party shall not be performed by or delegated to the tobacco industry.

13. Each Party shall ensure that its competent authorities, in participating in the tracking and tracing regime, interact with the tobacco industry and those representing the interests of the tobacco industry only to the extent strictly necessary in the implementation of this Article.

14. Each Party may require the tobacco industry to bear any costs associated with that Party's obligations under this Article."

ANNEXURE 2: ARTICLE 15 AND 16 OF THE REVIEWED TOBACCO PRODUCTS DIRECTIVE

Article 15

Traceability

1. Member States shall ensure that all unit packets of tobacco products are marked with a unique identifier. In order to ensure the integrity of the unique identifier, it shall be irremovably printed or affixed, indelible and not hidden or interrupted in any form, including through tax stamps or price marks, or by the opening of the unit packet. In the case of tobacco products that are manufactured outside of the Union, the obligations laid down in this Article apply only to those that are destined for, or placed on, the Union market.
2. The unique identifier shall allow the following to be determined:
 - (a) the date and place of manufacturing;
 - (b) the manufacturing facility;
 - (c) the machine used to manufacture the tobacco products;
 - (d) the production shift or time of manufacture;
 - (e) the product description; (f) the intended market of retail sale;
 - (g) the intended shipment route;
 - (h) where applicable, the importer into the Union;
 - (i) the actual shipment route from manufacturing to the first retail outlet, including all warehouses used as well as the shipment date, shipment destination, point of departure and consignee;
 - (j) the identity of all purchasers from manufacturing to the first retail outlet; and
 - (k) the invoice, order number and payment records of all purchasers from manufacturing to the first retail outlet.
3. The information referred to in points (a), (b), (c),(d),(e),(f),(g) and where applicable,(h) of paragraph 2 shall form part of the unique identifier.
4. Member States shall ensure that the information mentioned in points (i), (j) and (k) of paragraph 2 is electronically accessible by means of a link to the unique identifier.
5. Member States shall ensure that all economic operators involved in the trade of tobacco products, from the manufacturer to the last economic operator before the first retail outlet, record the entry of all unit packets into their possession, as well as all intermediate movements and the final exit of the unit packets from their possession. This obligation may be complied with by the marking and recording of aggregated packaging such as cartons, master cases or pallets, provided that the tracking and tracing of all unit packets remains possible.
6. Member States shall ensure that all natural and legal persons engaged in the supply chain of tobacco products maintain complete and accurate records of all relevant transactions.
7. Member States shall ensure that the manufacturers of tobacco products provide all economic operators involved in the trade of tobacco products, from the manufacturer to the last economic operator before the first retail outlet, including

importers, warehouses and transporting companies, with the equipment that is necessary for the recording of the tobacco products purchased, sold, stored, transported or otherwise handled. That equipment shall be able to read and transmit the recorded data electronically to a data storage facility pursuant to paragraph 8.

8. Member States shall ensure that manufacturers and importers of tobacco products concluded data storage contracts with an independent third party, for the purpose of hosting the data storage facility for all relevant data. The data storage facility shall be physically located on the territory of the Union. The suitability of the third party, in particular its independence and technical capacities, as well as the data storage contract, shall be approved by the Commission.

The third party's activities shall be monitored by an external auditor, who is proposed and paid by the tobacco manufacturer and approved by the Commission. The external auditor shall submit an annual report to the competent authorities and to the Commission, assessing in particular any irregularities in relation to access.

Member States shall ensure that the Commission, the competent authorities of the Member States, and the external auditor have full access to the data storage facilities. In duly justified cases the Commission or the Member States may grant manufacturers or importers access to the stored data, provided that commercially sensitive information remains adequately protected in conformity with the relevant Union and national law.

9. Recorded data shall not be modified or deleted by an economic operator involved in the trade of tobacco products.
10. Member States shall ensure that personal data are only processed in accordance with the rules and safeguards laid down in Directive 95/46/EC.
11. The Commission shall by means of implementing acts:
 - (a) determine the technical standards for the establishment and the operation of the tracking and tracing system as provided for in this Article, including the marking with a unique identifier, the recording, transmitting, processing and storing of data and access to stored data;
 - (b) determine the technical standards for ensuring that the systems used for the unique identifier and the related functions are fully compatible with each other across the Union.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 25(2).

12. The Commission shall be empowered to adopt delegated acts in accordance with Article 27 to define the key elements of the data storage contracts referred to in paragraph 8 of this Article, such as duration, renewability, expertise required or confidentiality, including the regular monitoring and evaluation of those contracts.
13. Paragraphs 1 to 10 shall apply to cigarettes and roll-your-own tobacco from 20 May 2019 and to tobacco products other than cigarettes and roll-your-own tobacco from 20 May 2024.

Article 16

Security Feature

1. In addition to the unique identifier referred to in Article 15, Member States shall require that all unit packets of tobacco products, which are placed on the market, carry a tamper proof security feature, composed of visible and invisible elements. The security feature shall be irremovably printed or affixed, indelible and not hidden or interrupted in any form, including through tax stamps and price marks, or other elements imposed by legislation.

Member States requiring tax stamps or national identification marks used for fiscal purposes may allow that they are used for the security feature provided that the tax stamps or national identification marks fulfil all of the technical standards and functions required under this Article.

2. The Commission shall, by means of implementing acts, define the technical standards for the security feature and their possible rotation and adapt them to scientific, market and technical developments.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 25(2).

3. Paragraph 1 shall apply to cigarettes and roll-your-own tobacco from 20 May 2019 and to tobacco products other than cigarettes and roll-your-own tobacco from 20 May 2024.

ANNEXURE 3: CASE STUDIES

PHARMACEUTICALS

The United States Food and Drug Administration estimates that in some parts of the world between 30 and 50 % of drugs to treat serious diseases are counterfeit.¹⁴¹ The global pharmaceutical industry is currently facing massive problems with counterfeiting, theft, channel diversion and false returns to manufacturers.

Companies that operate within the industry and governments worldwide believe that product serialization can significantly reduce counterfeiting. Serialization intends to ensure tracking and tracing of the product through the entire supply chain, given the use of a unique serial number that identifies the product, in addition to origin, batch number and its expiry date. The objective is that serialization will allow the product's lifecycle to be traced from production, through distribution and finally to dispensation to patients at the drugstore/pharmacy or hospital.

DRIVERS – COUNTERFEITING AND PUBLIC HEALTH

Because of the major negative impact counterfeits are having on public health, it is vital that the pharmaceutical supply chain be controlled to ensure that all pharmaceutical products are genuine, stored, transported and handled in suitable conditions. Controlling the supply chain will also allow officials to focus their efforts on finding the dangerous counterfeit products.

REQUIRED LEGISLATION

The EU Directive 2001/83/EC was created to address the issue of falsified medicinal products and the threat they were causing to public health and safety. This Directive was amended in 2011 (but came into force in 2013) with Directive 2011/62/EU which introduced new, harmonized EU-wide measures to ensure safety of medicinal products by instating rigorous controls.

The key objective of the Directive was to address the increase of falsified drugs and medicines found in the EU, by:


- Improving quality controls on active substances and excipients,
- Requiring safety features for medicines at risk of counterfeiting,
- Regulating medicines imported for re-export (new term -"introduced") and rules governing access to medicines held in free trade zones and warehouses,
- Strengthening obligations on wholesale dealers and extending regulation to brokers of medicines,
- Addressing internet supply of medicine (evidence of rising issues around this subject is that Google Inc. had to agree on a \$500 million forfeit for allowing online Canadian pharmacies to place advertisements through its AdWords program targeting consumers in the United States, resulting in the unlawful

¹⁴¹ <http://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/CounterfeitMedicine/UCM235240.pdf>







importation of controlled and non-controlled prescription drugs into the United States), and

- Strengthening inspection and ensuring appropriate penalties for counterfeiting are in place in Member States.

A unique solution for ensuring track and trace is not yet available in Europe, but countries have adopted diverse alternatives, as shown in the diagram below. The European Federation of Pharmaceutical Industries and Associations (EPFIA) – is however working towards the adoption of a single solution for the industry. There are also discrepancies among the individual EU Member States’ legislation despite the fact that Directives 2001/83/EC3 and 2011/62/EU set the ground rules for harmonization.



■ Countries with active track and trace solutions for medicines

Country	Type of Solution	Data	Coding Types
Italy	Label	Product code Other data	• Bar code EAN-32 
Belgium	Label	Product code	• Bar code EAN-128 
France	Label	Product code	• Bar code EAN-13 
Portugal	Direct Printing	Product code	• Bar code EAN-39 
Nederlands	Label	Product code	• Bar code EAN-128 
Spain	Direct Printing	Product code Other data	• 2D code PDF 417 

On a broader perspective, it can be stated that a considerable number of countries throughout the world are working towards implementing legislation and solutions that aim to achieve value chain-wide tracking and tracing of products:

- **USA:** The Drug Quality and Security Act (DQSA - H.R. 3204) which was signed by President Obama on Nov. 27, 2013 has pre-empted any state laws including the California ePedigree and the existing Florida legislation. Item level serialization will be pushed to 2017 but lot level tracking is required starting January 2015. Full aggregation is only foreseen not until 2023.
- **China** has legislation that manufacturers have to request serial numbers for products to be produced in or to be imported into China and then report the actual serial numbers to the China FDA once they have been produced or imported.
- **Turkey** is also running a comprehensive track and trace infrastructure. Initially meant to combat insurance fraud, it is now tracking and tracing all products entering Turkey. However, information obtained showed that the solution crashed on the first day of operation due to high volumes that were not planned for from the outset of the initiative.
- **India** has established legislation for all products **exported** from India. There are currently no requirements for government reporting, but manufacturers have to keep the serialized data to be able to verify single packages on request.
- **Korea’s** legislation for serialization will become effective in 2015 and includes government reporting. No details have been published yet on how this is supposed to work. Such details are expected by the end of May 2014, which

would probably impact the effective date of the legislation, as this would not leave enough time to implement the requirements.

- **Argentina's** legislation is effective but limited to certain products. However the number of products falling under this legislation is rapidly growing. Administración Nacional de Medicamentos, Alimentos y Tecnología Médica (ANMAT) has recently (Jan 30, 2014) published a detailed specification of Argentina's central database within the Sistema Nacional de Trazabilidad de Medicamentos.
- **Brazil** has had legislation on the books for quite some time, but it was not implemented. A new set of guidelines was published by the end of 2013 which will become effective in 2016. The regulation requires serialization and government reporting. The current interpretation makes the manufacturer responsible for the entire supply chain, which spurred some debate on this requirement.

IMPLEMENTATION

Directive 2011/62/EU introduces mandatory 'safety features' to allow the verification of the authenticity of medicinal products for human use ('unique identifier') and places the Commission under an obligation to adopt delegated acts setting out the details relating to the unique identifier (2014 – for implementation in 2017).

A concept paper was launched in November 2011 for public consultation in order to prepare both the impact assessment and the delegated act. The European Federation of Pharmaceutical Industries and Associations (EFPIA) and the European Directorate for the Quality of Medicines and HealthCare (EDQM) created recommendations. Both approaches currently seem to lean towards a common approach:

- Both EFPIA and EDQM recommend GS1 Standard and the 2D Matrix Code
- Both systems embrace the use of national identifiers according to national law (NTINs)
- Both systems embrace a central hub or central system
- The delegated act will provide information on the selected approach



EDQM is a directorate of the "Council of Europe," which is the continent's leading human rights organization with 47 Member States, 28 of which are members of the European Union. EDQM has launched the eTACT Project that aims to establish a pan-European system for tracking serialized packages of medicine. According to EDQM, its scope is wider than EFPIA's as it includes patients, consumers and Internet pharmacies, and it also provides the option for serial number aggregation.



EFPIA represents the pharmaceutical industry in Europe. In collaboration with organizations representing wholesalers, re-packagers, and pharmacies/chemists, they define the "European Stakeholder Model" (ESM). ESM partners have built an "EU-wide coding and serialization system", called European Medicines Verification System (EMVS). The aim is to set the standard for "Serialized Track and Trace" in the European Union.

EMVS is intended to allow for verification of packages at the point of dispensing; however, any member of the supply chain may verify the originality of a package at any point. EMVS allows national systems (with specific national requirements) to be connected via a pan-European hub. This would allow any member of the supply chain to check the originality of any pharmaceutical product against one single access point regardless of which country the data resides.

EFPIA has scheduled 2 pilots so far, the first one in Sweden and the second one in Germany. It is expected that the German pilot (SecurPharm) will be implemented in Germany.

A joint paper from EAEPC, EFPIA, GIRP and PGEU states that ESM represents a practical and cost-effective means of implementing the requirements of the EU Falsified Medicines Directive in Europe, for the following reasons:

- A system that is designed and run by those who will use it day-to-day (pharmaceutical manufacturers, pharmacists, wholesalers and parallel distributors) best assures the timely, secure and cost-effective implementation of a product verification system;
- The de-centralized structure of the ESM will permit highly flexible implementation at national level; and
- The efficiency and effectiveness of the ESM have already been successfully demonstrated by a pilot in Sweden in 2009-2010.

EFPIA recommends the adoption of a unique standard for the coding of pharmaceutical products across Europe based on the 2D Data Matrix ECC-200 to be introduced on all secondary packaging of prescription products sold in Europe. The data encoded in the unique marking applied to pharmaceutical packs includes:

- Product code
- Serial number
- Expiry date
- Lot number (batch code)

EFPIA and the above mentioned organizations that have defined the ESM envisage a series of national data repositories (linked via a European Hub and together forming the EMVS), that serve as the verification platforms which pharmacies and other registered parties can use to check a pack's authenticity. The system will be interoperable between EU Member States with flexibility to account for national needs. In schematic form (Source: EFPIA):

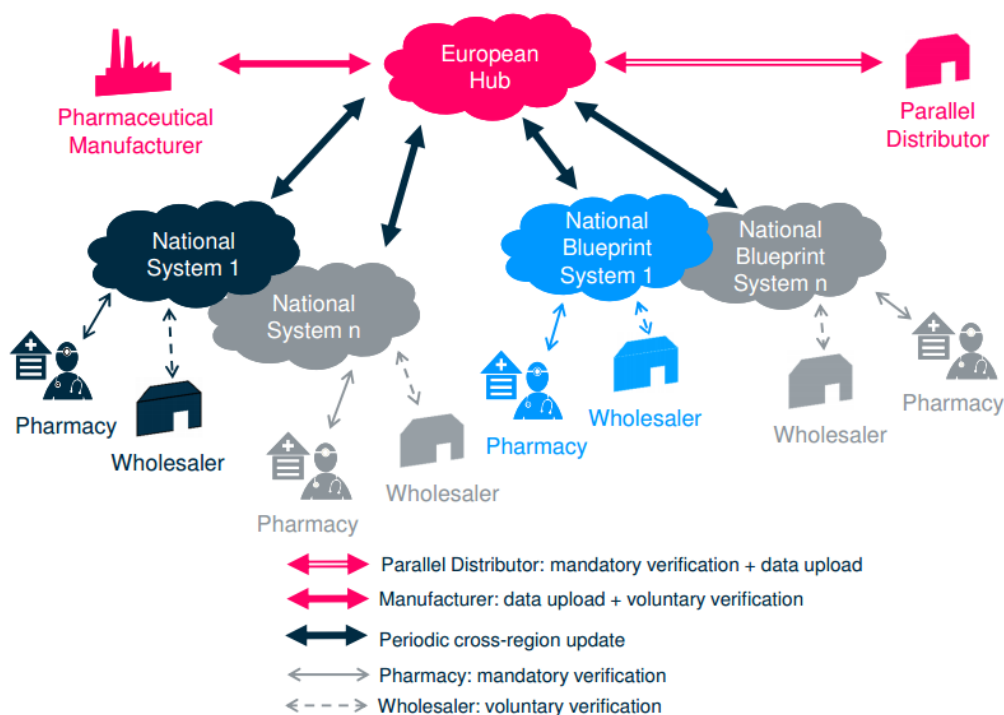


Figure 105 - Europe Medicines Verification System (Source: EFPIA)

National Blueprint Systems (at the right of the picture) are a way to allow national stakeholders to join the EMVS without the need to build a separate, national system.

In regards to the EDQM’s approach – eTACT – the objective is similar: to ensure traceability of individual packs of medicines/drugs using mass serialization. It is based on the principle of generating a Unique Medicine Identifier (UMI) at the manufacturing stage.

As a public, intergovernmental organization, EDQM promotes public governance for the eTACT system to ensure confidentiality of data handled by the system.

The project is currently restricted to the traceability of secondary packaging. It is designed for any medicinal product and is opened to any registered business stakeholders willing to join the project. All 37 Member States of the European Pharmacopoeia are eligible to use eTACT. A diagram showing the involvement of different stakeholders follows.



Source: www.edqm.eu

eTACT’s scope covers any pharmaceutical product, allowing any registered business stakeholders, authorities and patients to check the authenticity of medicines/drugs at a secondary packaging level.

The UMI can be traced and verified by the different stakeholders in the legal supply chain. Verification must be performed at the dispensing stage.

Patients are also allowed to verify the authenticity of their medication (through mobile phone applications), which is a unique feature of the EDQM project that will significantly contribute to strengthening the public’s confidence in the legal supply chain.

eTACT also covers Internet and mail-orders with traceability and UMI verification.

In March 2014, EDQM announced the launch of a new database called “Know-X” that collates reports on counterfeit/falsified medical products that have been detected in Council of Europe Member States. As mentioned on the EDQM website the database contains details on closed cases of counterfeit/falsified medical products, technical information on the testing performed, the authorities involved and what actions were taken. The information provided is gathered from various sources (Official Medicine Control laboratories, health authorities, regulatory agencies, medical products surveillance authorities, customs and police) and it is intended to provide governments with decision aids for the management and prevention of specific risks.

KEY LEARNINGS FROM THE PHARMACEUTICAL EXPERIENCE

Pharma is a highly regulated industry and legislative objectives are similar to those in the tobacco industry – mainly to protect the consumer’s health. The following describes some key learnings from the Pharmaceutical industry that could be relevant in the Tobacco Domain:

- Interoperability between EU Member States is critical both where goods move amongst Member States within the internal market, as well as the providing a platform to allow for a uniform view of tracking and tracing information within the value chain
- Flexibility is required to account for national needs, avoiding over investing or under investment in accordance to countries’ requirements

- Safety features and technical specifications are similar in intent to those, as published in the TPD
- A FAQ-like section helps to clear doubts regarding scope, governance and technicalities
- Use of passive RFID is possible but considered not workable at the current stage
- Solutions tend not to fully respond to track and trace requirements

EXPLOSIVES

OVERVIEW

Terrorists have used trucks filled with explosives in some of the worst terrorist attacks in history. In Mumbai India on 13 July 2011 a terrorist attack killed more than one hundred people, wounded hundreds of others and destroyed a federal building with a truck carrying common agricultural chemicals. Small quantities of explosives were used in Madrid on 11 March 2004 terrorist attacks. The risk of explosives to fall into the hands of terrorists and the threats of terrorism attacks led the EU to adopt security measures for explosives in all stages of the supply chain.

Additionally, on 15 January 2013, Regulation (EU) No 98/2013,¹⁴² on the marketing and use of explosives precursors, was adopted with a view to enhance protection of consumers from the threat of terrorism. The Regulation, which shall come into force 2 September 2014, establishes a tighter regulatory regime for high-risk chemical explosive precursors to reduce their accessibility to the general public (private individuals). The Commission is now, in consultation with stakeholders, preparing guidelines for its implementation.

DRIVERS - COUNTERTERRORISM

Counter-terrorism is the main reason to control the supply chain to avoid leakage into terrorist and criminal rings, in particular in the south of Europe, where many laws were developed in response to specific terrorist or criminal threats (ETA in Spain, France and Portugal, the IRA in the UK, and the Mafia in Italy). France, Spain and the UK are amongst the strictest in the EU regarding security arrangements.

The lack of systematic data collection at the EU level has also contributed to the establishment of a track and trace system to reinforce existing legislation (e.g. in Portugal, unexploded products must be returned to the manufacturer if not used during the same day).

REQUIRED LEGISLATION

In April 2004, the Commission adopted Decision 2004/388/EC, later amended by the Commission Decision 2012/347/EU, which harmonizes the requisite information and procedures to be followed for the transfer of explosives for civil uses between Member States.

¹⁴² <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:039:0001:0011:EN:PDF>

However, it is only with the adoption of the Action Plan on Enhancing the Security of Explosives by the Council in 2008 that serialization came into play: EU directives 2008/43/E¹⁴³ amended by 2012/04/EU¹⁴⁴ are imposing marking of a unique identifier using a GS1 standard (1D barcode or 2D Data matrix) on all products containing explosives manufactured or imported into the EU for civil uses starting from 5 April 2013 onwards. A two year period is granted before all the data has to be readily accessible 24/7 for a period of 10 years after delivery.

IMPLEMENTATION

The mandatory data on the product is relatively succinct: the origin (country and site code) as well as a serial unique identifier.

- AI(90) -- Country/Site code (5 digits)
- AI(250) -- Secondary Serial Number (15 to 30 digits)

An example of a completed code would be:

(90)AT123(250)0123456789012345678901234567890

Additionally, but not compulsory, the Federation of European Explosives Manufacture (FEEM) also recommended taking advantage of this legal imposition to store additional business data¹⁴⁵ such as:

- AI(240) - Stock Keeping Unit SKU (up to 35 digits)
- AI(10) – Batch Number (up to 20 characters)
- AI(95) – Unit of Measure (in practice up to 3 letters)

An example of a complete code would be:

(240)012345678912345678(10)BATCH01(95)123456



Figure 106 - Example of products containing explosives requiring serialisation

¹⁴³ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:094:0008:0012:EN:PDF>

¹⁴⁴ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:050:0018:0020:EN:PDF>

¹⁴⁵ <http://feem.info/wp-content/uploads/2013/01/Guidance-Note-FEEM-European-Code-Structure-Mod.1-April-2013.pdf> (accessed 22/04/2013).



Figure 107 - Example of product label compliant with the new directive

As part of the recommended measures, establishment of an EU-wide Early Warning System (EWS), which should notify the relevant national authorities of any potential threats following missing or stolen explosives¹⁴⁶. Such a system would be used in order to exchange information concerning:

- Immediate threats
- Theft of explosives
- Theft of detonators
- Theft of precursors
- Suspicious transactions
- Discovery of new *modi operandi*

The system should be available in particular to Member States public security authorities (national contact points), Europol and all operational Explosive Ordnance Disposal (EOD) units.

COMMONALITIES AND DIFFERENCES WITH TOBACCO

There are some similarities between the traceability solutions developed for explosives that could offer some key learning's for a traceability solution for tobacco:

- Certain mechanisms will have to be put in place to share information with intelligence agencies (EUROPOL, FRONTEX). "Real-time" is strongly suggested to increase capacity to react quickly;
- Each manufacturing site shall be given a three-digit code by the national authority¹⁴⁷ of the Member States where it is established. Mechanisms to do so should be analysed to determine the best practices and lessons for tobacco;
- The regulation does mention regular tests to insure integrity and soundness of the data collected. This should warrant special attention in the implementation

¹⁴⁶ [Council of the European Union, EU Action Plan on Enhancing the Security of Explosives, 15175/08. 4.8.2008.](#)

¹⁴⁷ http://ec.europa.eu/enterprise/sectors/chemicals/files/explosives/national-authorities-explosives_en.pdf

of the TPD (including periodicity, scope, who is responsible, oversight, etc.); and

- A FAQ¹⁴⁸ will help to address ambiguities of the implementation of the directive. This will help smaller players to address and remain compliant.

There are some key differences highlighted between the two domains that makes the traceability solutions for explosives less suitable for the tobacco domain:

- No randomization of the serial number required (easier to counterfeit or estimate volume of product for competitive intelligence purposes)¹⁴⁹;
- It is the manufacture's responsibility to store the data, with supervision from the Member State. FCTC recommendations render this unlikely for the tobacco domain. Specifications for record keeping seem vague. Also, it is to be performed by the last operator before use;
- Use of passive RFID is mentioned, but only as an additional measure (not replacing the marking itself). This is, however, a common point with the pharmaceutical domain;
- Manufacturers have no apparent financial gain in circumventing the system, maybe not so from smaller logistics actors and/or distributors that could be tempted to sell explosives to un-licensed parties for profit; and
- Volume of data not comparable to those of Tobacco Industry.

WINE / ALCOHOL

OVERVIEW

Counterfeit wines are estimated to account for as much as five percent of the secondary market, according to the Wine Spectator. For centuries, most wineries made little effort to make sure their wines could not be counterfeited. But now, concerned that customers will lose confidence and stop buying their wine, wineries are exploring ways to make sure future bottles can be authenticated. Unfortunately, even the most advanced RFID technologies cannot absolutely ensure that the product inside the bottle is genuine. New technologies that allow vintners, collectors, auction houses and law enforcement to easily validate the authenticity of their products are needed.¹⁵⁰

The global alcoholic drinks industry is expected to exceed \$1 trillion in 2014, according to MarketLine. Market volume is predicted to reach almost 210 billion litres in 2014, a 10% increase in five years. Beer, cider and flavoured alcoholic beverages represent the leading market segment with over half of the overall market value. The EU represents almost 57% of the world alcoholic drinks market.¹⁵¹ The industry is fragmented with the three leading companies holding almost 40% of overall market volume. The market is led by Anheuser-Busch InBev, which has over 20% of the overall market volume.¹⁵²

¹⁴⁸ http://ec.europa.eu/enterprise/sectors/chemicals/files/explosives/qa_for_website_en.pdf

¹⁴⁹ RxTrace | Randomization — An Interview with Ken Traub — Part 2: Properties of Randomization - <http://www.rxtrace.com/2014/04/randomization-an-interview-with-ken-traub-part-2-properties-of-randomization.html/> (accessed 23/04/2014)

¹⁵⁰ <http://www.adnas.com>

¹⁵¹ <http://www.reportlinker.com>

¹⁵² Ibid.

DRIVERS – FOOD SAFETY AND PUBLIC HEALTH

The rise in illicit and counterfeit food and beverage (including alcohol) products and the need to protect consumer health are the main drivers behind food track and trace systems. It is vital to ensure that all stages of the value chain (production, processing and distribution) are adequately monitored, with the objective to provide consumers with safe, authentic products.

EC Regulation No. 178/2002 outlines the general principles that must be implemented on the subject of “food and feed” in order to protect the interests of consumers. It established the European Food Safety Authority, which regulates all stages of production, processing and distribution of food and feed. Moreover, EU Regulation No. 1169/2011 establishes the general principles, requirements and responsibilities governing food information, in particular mandatory food labelling requirements.

In regards to wine, Council Regulation No 479/2008 specifies rules applying to the production and marketing of wine. Particularly, it details rules in regards to the vineyard register, compulsory declarations and the documents accompanying consignments of wine products.

▪ LIST OF MANDATORY PARTICULARS:

- The designation for the category of the grapevine product
- The actual alcoholic strength by volume
- An indication of provenance
- An indication of the bottler
- An indication of the importer in the case of imported wines
- An indication of the sugar content (only in the case of sparkling wine)
- The term ‘protected designation of origin’ or ‘protected geographical indication’ and the name of the protected designation of origin or geographical indication, for wines with a protected designation of origin or geographical indication

▪ LIST OF OPTIONAL PARTICULARS:

- The vintage year
- The name of one or more wine grape varieties
- For wines with a protected designation of origin or geographical indication, traditional terms
- Traditional terms, for wines with a protected designation of origin or geographical indication
- Terms referring to certain production methods
- The name of another geographical unit that is smaller or larger than the area underlying the designation of origin or geographical indication, for wines bearing a protected designation of origin or geographical indication

IMPLEMENTATION

In 2003, GS1 co-established the Wine Traceability Working Group together with the British Wine and Spirit Association (WSA) and its French counterpart - Association Française des Eleveurs, Embouteilleurs et Distributeurs de Vins et Spiritueux (AFED). The objective was to adapt the GS1 System for implementation by the wine industry to facilitate compliance with the traceability-related provisions of the General Food Law - Council Regulation (EC) No. 178/2002.

GS1 recommends using the following GS1 Traceability Tools in the context of wine:

- Global Location Number - numeric code that identifies organisation or physical entity
- Global Trade Item Number - number used for the unique identification
- Serial Shipping Container Code - a number used for the unique identification of logistic units
- Application Identifier - variable information, such as a batch number, production date or customer purchase order. This information is bar coded in the GS1-128 bar code symbol.
- Bar Codes and RFID - GS1 bar codes allow automatic data capture of GS1 numbers

Although work has been done primarily with the involvement of wine industry companies supplying to the EU, the focus has been on building a traceability model that has global applicability.

The Wine Traceability Working Group is comprised of representatives of international wine trading companies from France, Germany, South Africa, United Kingdom and the United States. Industry peers in Argentina, Australia, Chile, New Zealand, Spain, and other wine regions have also collaborated.

On the alcoholic beverages industry front, some solutions exist and are currently used in several countries, (e.g. Brazil, Canada, France, Italy, Morocco, Turkey and the United States), the majority being related to brand protection, rather than track and trace features. Providers like InkSure, Kodak, ProofTag, SICPA, Scriba, Zorya, amongst others, offer solutions that help consumer protection and enforcement agencies to track and trace the whole value chain.

The following three examples outline some of the main characteristics of solutions currently in use:

PROOFTAG

- ProofTag Bubble Tag was implemented at wine producers Comtes von Neipperg. In the face of fraud and its negative image and reputation of the brand, Stephan von Neipperg decided in 2006 to equip all its bottling lines with a unique tracing facility. Each label is serialized with 2D Data matrix code. This identifier enables tracing all along the supply chain.

SICPA

- In Brazil, the SICOBE application counts, records, authenticates and monitors all beer (soft drinks and water too) production on manufacturing lines regardless of the manufacturers of beverage brands.
- The system identifies and classifies brands and beverage types in real time on high-speed production lines (processing over 1200 products a minute). A Vision System was tailored to the classification of beverage products, which, together with a secure code printed on each product, ensured full monitoring of production and the extended value chain.

ZORYA

- In Georgia, Zorya security printing developed a system automating real time monitoring of production, importation, distribution and tax status of excise and other specific products; the system is to be applied to the domestically manufactured, imported and exported products (in case of purchase request).
- The system provides real time monitoring of the entire life cycle of the goods through use of the highly secured control stamp with unique machine-readable marking.

COMMONALITIES AND DIFFERENCES WITH TOBACCO

There are some similarities between the traceability solutions developed for wine that could offer some key learnings for a traceability solution for tobacco:

- Common motivations for implementation;
- Share with law enforcement/customs agencies;
- Each manufacturing site shall be attributed a code by the national authority of the Member States where it is established;

- Responsibility of storing the data is the manufacturer with supervision from the Member State;
- Real-time is suggested as being of added-value; and
- Randomization of the serial numbers.

There are some key differences highlighted between the two domains that make the traceability solutions for wine less suitable for the tobacco domain:

- Limited usage by small producers/manufacturers (particularly in regard to wine);
- Some solutions tend not to fully respond to track and trace requirements (rather brand protection); and
- Aggregation of serialized items is not yet under the radar for some of these solutions.

TOYS

OVERVIEW

The ability to recall products – including toys - from the market, is a necessary part of any safety legislation. If existing quality and safety checks fail to detect an issue prior to sale, a systematic method of notifying the public and removing potentially hazardous products from the market is needed. Some toys are discovered to have been unsafe after having been placed on the market.

From the recall perspective, it is notable that toy manufacturers may have to rely on third party, overseas manufacturers to produce the toys to specification. Even though the number of overseas manufacturers that the toy manufacturer works with can be limited, the distribution networks for toys are typically very large. The toy manufacturer needs to keep track of product numbers and model numbers as well as production dates and the manufacturer involved.

DRIVERS - THE IMPORTANCE OF AN EFFECTIVE RECALL MANAGEMENT SYSTEM

There are numerous examples of recalls of toys, the most notable of which include the toy company Mattel recalling over 1.5 million toys in 2007 due to toxic lead paint on its toys. After the lead paint scandal in 2007, the Chinese government created a recall system for unsafe food products and toys.

Number of Recalls by Product Category		Recalls by hazard – top 5		Recalls by country – top 5	
Child Products (not including toys)	1267	Fire and Fire-Related Burns	1562	China	2124
Toys	889	Choking	837	US	685
Other	2,939	Laceration	503	Taiwan	299
		Fall hazard	489	Mexico	106
		Electric shock	392	Hong Kong	91

Source: US Consumer Product Safety Commission, April 2013

Product safety has gained an increasingly global dimension as a consequence of increased cross-border trade and more sophisticated supply chains and product designs. At the same time, world merchandise exports have shifted from developed to developing and emerging economies over the last 60 years.

Over the same period, the number of recalled products has increased. From 1992 to 2006, toy recalls increased at a faster rate than the increase in imports from foreign countries in the United States. This trend was also observed in the EU, which shared 1,803 notifications via its RAPEX (the EU Rapid Information System for non-food products) information-sharing system in 2011, compared to 139 notifications in 2003.

Moreover, consumers tend to shop online more frequently. OECD countries' share of consumer purchasing products via e-commerce increased from about 25% of individuals in 2007 to 32% in 2011. Brazil's online sales increased by 26% between 2011 and 2010, while China achieved a 500% growth in 2011, compared to 2008. In the EU, almost a third of consumers made at least one purchase in another EU country in 2011, which represents a 5% growth compared to 2006.

In this changing market landscape, national authorities, businesses and governments have to respond more swiftly to address these issues. Global recall systems provide an important source of information for taking more timely and effective actions to protect consumers at every step of the global supply chain.

APPLICABLE LEGISLATION IN THE EUROPEAN UNION

Union harmonisation legislation foresees requirements for the traceability of products on the market, but does not stipulate how to achieve or implement these requirements. The legislation is technology-neutral and does not prescribe the technology to be used, such as printing or moulding. It allows market surveillance authorities to quickly get in contact with the economic operator responsible for the placing of an unsafe or non-compliant product on the Union market.

A dangerous product identified in one EU member country triggers an alert throughout Europe, but new rules are aimed at improving the speed with which the source can be traced with the requirement that manufacturers must ensure that each toy can be traced back to the factory where it was made.

EU harmonisation legislation requires manufacturers to meet the following requirements:

- Name,
- Registered trade name or registered trade mark and
- The address at which they can be contacted,

- A type, batch, serial or model number or other element allowing their identification,
- On the product or, where that is not possible, on its packaging or in a document accompanying the product,
- That will allow it to identify any economic operator who has supplied them with a product and any economic operator to whom they have supplied a product (“one up, one down”).

Importers are required to indicate the following elements:

- Name
- Registered trade name or registered trade mark
- Address at which they can be contacted, on the product or, where that is not possible, on its packaging or in a document accompanying the product

EU RAPID ALERT SYSTEM FOR NON-FOOD DANGEROUS PRODUCTS

The recall of consumer products such as toys in the EU relies on the RAPEX (the EU Rapid Information System for non- food products). This system allows EU Member States and the European Commission to share information quickly and efficiently about dangerous products found on the European market and to inform consumers about potential risks to their health and safety.

Since its creation in 2004, the RAPEX system has been instrumental in protecting European consumers’ health and safety. It provides a platform for the exchange of information on dangerous products between Member States and the European Commission. Toys accounted for 25% of RAPEX notifications, highlighting the need to have clear methods to identify products.

THE OECD GLOBAL RECALLS PORTAL

The launch of the **OECD Global Recalls Portal** in 2012 set an important milestone for the promotion of consumer protection worldwide. The GlobalRecalls portal brings together information on product recalls being issued around the world, on a regular basis, together in one place – on an OECD platform.¹⁵³

¹⁵³ <http://globalrecalls.oecd.org>



The GlobalRecalls portal brings together information on product recalls being issued around the world, on a regular basis, together in one place – on an OECD platform.

The portal includes information on mandatory and voluntary consumer product recalls which were issued by a governmental body and were made publicly available.

Global portal on product recalls

- > **Search for recalls**
- > About the portal
- > How to use this portal
- > Benefits of the portal
- > Project partners
- > Endorsements
- > Official launch
- > About us
- > Jurisdiction's web sites

Free text search

Product name Manufacturer

Jurisdiction where recalled where made

Date And/Et

Records: 116
Showing: 1 - 25

Date	Picture	Product name	Jurisdiction of recall	Language	Details	Provider Link
December 2013		toys "r" us--nantucket 4-in-1 cot	Australia	English	Details	Provider details
October 2013		zapatin import pty ltd--assorted children's wooden toys	Australia	English	Details	Provider details
July 2013		toys r us--fast lane fa-005 radio-control 3-channel helicopter	Australia	English	Details	Provider details
April 2013		hong zhi toys	Estonia	English	Details	Provider details

TRACK AND TRACE REQUIREMENTS: USA

Products that are designed or intended primarily for use by children must have distinguishing permanent marks (generally referred to as “tracking labels”) that are:

- Affixed to the product and its packaging and,
- Provide certain identifying information, including:
 - Manufacturer or private labeller name;
 - Location and date of production of the product;
 - Detailed information on the manufacturing process, such as a batch or run number, or other identifying characteristics;
 - Any other information to facilitate ascertaining the specific source of the product;
 - All tracking label information should be visible and legible; and
 - Could consist of a code and a website address, although consumers who do not have access to the Internet should also be able to know who to contact if they require further information.

Consumer Product Safety Act, 15 U.S.C. §2063(a)(5) (CPSA).

Consumer Product Safety Improvement Act of 2008 (CPSIA) (Public Law 110-314)

“Tracking label” is a shorthand term used in place of the phrase “distinguishing permanent marks” used in the legislation. The purpose of legislation in the US is to ensure:

- That manufacturers and consumers have sufficient information to easily enable a consumer to ascertain whether the product they possess is subject to a recall;

















- Aid in determining the origin of the product and the cause of the recall; and
- Facilitate the identification and removal of these products from the stream of commerce as soon as possible after the notice of a voluntary or mandatory recall.

VOLUNTARY TRACK AND TRACE PROGRAMMES AND VOLUNTARY RECALLS














Some form of traceability is already a legal requirement in certain sectors in the United States, Canada, the EU and some countries in Latin America, Asia and Africa. But beyond mandatory traceability, more and more manufacturers are voluntarily deploying traceability programs as part of their supply chains to improve efficiency and to help protect their brands and ensure that their products are safe.

Around 33% of all recalls in the EU are done on a voluntary basis, where producers proactively inform authorities of product safety issues and initiate a recall programme.



















ANNEXURE 4: EXISTING TAX STAMP PROGRAMES IN EU MEMBER STATES

Flag	State	Sent Survey	Tax Stamp Program	Stamp Picture *	Tax Stamp Volumes (2010)	Tax Stamp Provider (if Known)	Tax Stamp Features	Evidence of Track and Trace	Comments
	Austria	-	Not officially, but labels for wine quality	-	-	-	-	-	The Ministry of Agriculture issues seals for wine to ensure quality. Seals are incorporated into cap and include a state control number that denotes the producer. They monitor taxes based on quantity released.
	Belgium	Yes	Yes (Benelux)		833	Joh Enschede	Paper-based, wet glue type	Track and Trace, 2D Matrix Code	Printed in Intaglio, carry a calligraphic rosette with the intertwined initials of the three Benelux countries. Belgium recently upgraded to 2D Matrix Code.
	Bulgaria	Yes	Yes		805	Bulgarian National Bank Printing Works	Hologram & Microtext	Tracing	Introducing new tax stamp January 2014; using Goebel Overt Numeric Hybrid Printing (Tax Stamp News Dec 2012)
	Croatia	Yes	Yes		350	Agencija za Komercijlanu Djelatnost (AKD)	Hologram and unique serial number	-	-
	Cyprus	-	-	-	-	-	-	-	-
	Czech Republic	-	Yes		1038	State Printer	Paper Based	-	-
	Denmark	-	Yes		377	-	-	-	-
	Estonia	Yes	Yes		144.4	Vaba Maa	Hologram	Tracing – Invisible Datamatrix	They announced in 2011 they would implement track and trace system – have not found latest yet. Alcohol uses holographic label with alphanumeric serial code.
	Finland	-	Yes		230	-	-	-	-





EUROPEAN COMMISSION

Flag	State	Sent Survey	Tax Stamp Program	Stamp Picture *	Tax Stamp Volumes (2010)	Tax Stamp Provider (if Known)	Tax Stamp Features	Evidence of Track and Trace	Comments
	France	-	No, but methods to protect wine industry	-	-	-	-	-	Use bubbletags, taggants and RFID labels to protect wine
	Germany	Yes	Yes		4195	Bundesdruckerei	Paper Based	-	Tax Stamp report states that 2011 was a record year for illicit trade in Germany with close to 50% of market near borders with Eastern Europe. They claim it was because of poor Customs resources.
	Greece	Yes	Yes		1418	Matsoukis (Division of Giesecke Devrient)	-	-	-
	Hungary	Yes	Yes		700	ANY (Previously Allami Nyomda and Hungarian Banknote Printing)	Hologram, multicolour, 2D data matrix	Yes (Tracing) and according to Tax Stamp Report also tracking – see comments	Paper label, self-adhesive for OTP, with hologram and security fibers and microtext as well as serialization code and track and trace system (Tax Stamp Report)
	Ireland	Yes (Provider)	Yes		215	DLR Security Concepts	Microtexts and Mosaic patterns; bi-fluorescent inks and “up converting inks”	Tracing (potential Trace)	14 different visible and hidden features. Readable by handheld devices and consumers can identify genuine product. From tax stamp report, Irish Revenue Commissioner: “we also keep a reserve stamp to hand in case of an undetectable forgery or a large theft of genuine stamps. This stamp carries an upgrade design option (or sleeper) that can be easily activated at short notice.” Cited as smuggling capital of Europe.
	Italy	Yes	Yes		4,350	IPZS (Istituto Pografico e Zecca Dello Stato)	Paper based with Taggant	-	-
	Latvia	Yes	Yes		104	Delarue	Security Fibres, microtext, latent image, hologram, special inks (colour shifting, iridescent, thermo chromic, fluorescent, and infra red), alphanumeric code	-	Wet glue applied and self-adhesive. According to Tax Stamp Report there was no track and trace in place in 2012 but it was being considered. According to Stamp Tax News 2011, cigarette stamps are paper-based, while those for alcohol take the form of pressure-sensitive holographic labels affixed to the bottle caps. The last upgrades were in 2008 for cigarettes and 2010 for alcohol. They held a tender in 2011

EUROPEAN COMMISSION

Flag	State	Sent Survey	Tax Stamp Program	Stamp Picture *	Tax Stamp Volumes (2010)	Tax Stamp Provider (if Known)	Tax Stamp Features	Evidence of Track and Trace	Comments
	Lithuania	Yes	Yes		160	Garsu Pasaulis	-	- -	
	Luxembourg	Yes	Yes		170	Joh Enschede	-	- -	
	Malta	-	Yes		28	-	Holographic with serial numbering;	-	Uses full-face, pressure sensitive, self-adhesive, holographic label. Hologram not feature but the actual stamp.
	Netherlands	Yes	Yes (Benelux)		639	Joh Enschede	Paper-based, wet glue type	-	Printed in Intaglio, carry a calligraphic rosette with the intertwined initials of the three Benelux countries.
	Poland	Yes	Yes		2,900	PSPW (Polish Security Printing Works)	Watermark, security fibres, microtext, thermochromic ink, intaglio	Serialised - Tracing	Hidden security features include fluorescent ink, infrared ink and machine readable taggant. According to Tax Stamp Report no track and trace system in place as of 2012.
	Portugal	Yes	Yes		701	Imprensa Nacional Casa da Moeda, Opsec (hologram)	Colour, Microtext, Hologram with serial numbering	Yes – Tracing (uses Codentify code-on packs as pilot)	
	Romania	Yes	Yes		1,252	National Bank of Romania Printing House	Datamatrix, hologram	Yes – Tracing -	
	Slovakia	-	Yes		376	Prompt	-	- -	
	Slovenia	Yes	Yes		238	Garsu Pasaulis	-	Batch number -	

EUROPEAN COMMISSION

Flag	State	Sent Survey	Tax Stamp Program	Stamp Picture *	Tax Stamp Volumes (2010)	Tax Stamp Provider (if Known)	Tax Stamp Features	Evidence of Track and Trace	Comments
	Spain	-	Yes		3,820	FNMT (Fabrica Nacional de Moneda y Timbre Real Casa de la Moneda)	Paper-based	Traceability	Offset printed with numbering applied by letterpress and upgrade to be added to increase security and traceability according to printer in 2009 (Tax Stamp Report) to possibly include special inks, a coating to act as a carrier of features and QR codes for track and trace.
	Sweden	-	-	-	-	-	-	-	-
	United Kingdom	Yes	No	-	-	Unknown	Incorporated in Packaging (Taggants)		For tobacco, taggant based marker. Tax marks used as opposed to tax stamps. Since inception of marking, illicit trade decreased from 20% to 12% (2001-2009). As of 2010, for spirits they use a stamp (either free standing paper stamp or electronic label stamp) that includes a guilloche background, UV ink that excites and emits within a certain range, a forensic marker in the form of a chemical taggant, the signature of which is read with a hand held reader, and a serial number with an alpha-identifier denoting product type. The inks include invisible UV inks. Since the implementation of these stamps HMRC reported that there was a 30% increase from 2007 to 2008 in seizures of illicit products. May also have extended this to beer products.

* Image sources: <http://www.tax-stamp.com>

ANNEXURE 5: SURVEY PARTICIPANTS

Respondents included:

- Alpvision
- Arconvert
- Arjowiggins
- ATOS
- Axode
- Axway
- Bato & Divajn
- British American Tobacco
- Bundesdruckerei
- Data & Control Systems
- De La Rue
- Digital Coding & Tracking Association
- Domino Printing Sciences (Dps)
- Eastman Kodak Company
- Essentra
- Fracturecode Corporation
- Graphic Security Systems Corp
- Holoptica
- JDSU
- JTI
- Jura
- Kezzler
- Imperial Tobacco
- Laserlock Technologies
- Latent Image Technology
- Leonhard Kurz Stiftung & Co. Kg
- Movilizer Gmbh
- Nanotech Security Corporation
- Neenah Papers
- Omi Llc
- Optel Vision
- Pagemark Technology Inc.
- Polish Security Printing Works
- Printechnologies
- Prooftag
- Security Print Solutions
- Selinko
- Sicpa
- Systech International
- Technarts
- Tesa Scribos
- Vesdo Management To Technology (M2t)
- Yottamark
- Zorya Security Printing (Edaps Member).

ANNEXURE 6: SURVEY QUESTIONS AND EVALUATION CRITERIA

Annexure removed to protect confidential and proprietary information.

ANNEXURE 7: SUMMARY OF PROJECT ENGAGEMENTS

Annexure removed to protect confidential and proprietary information.

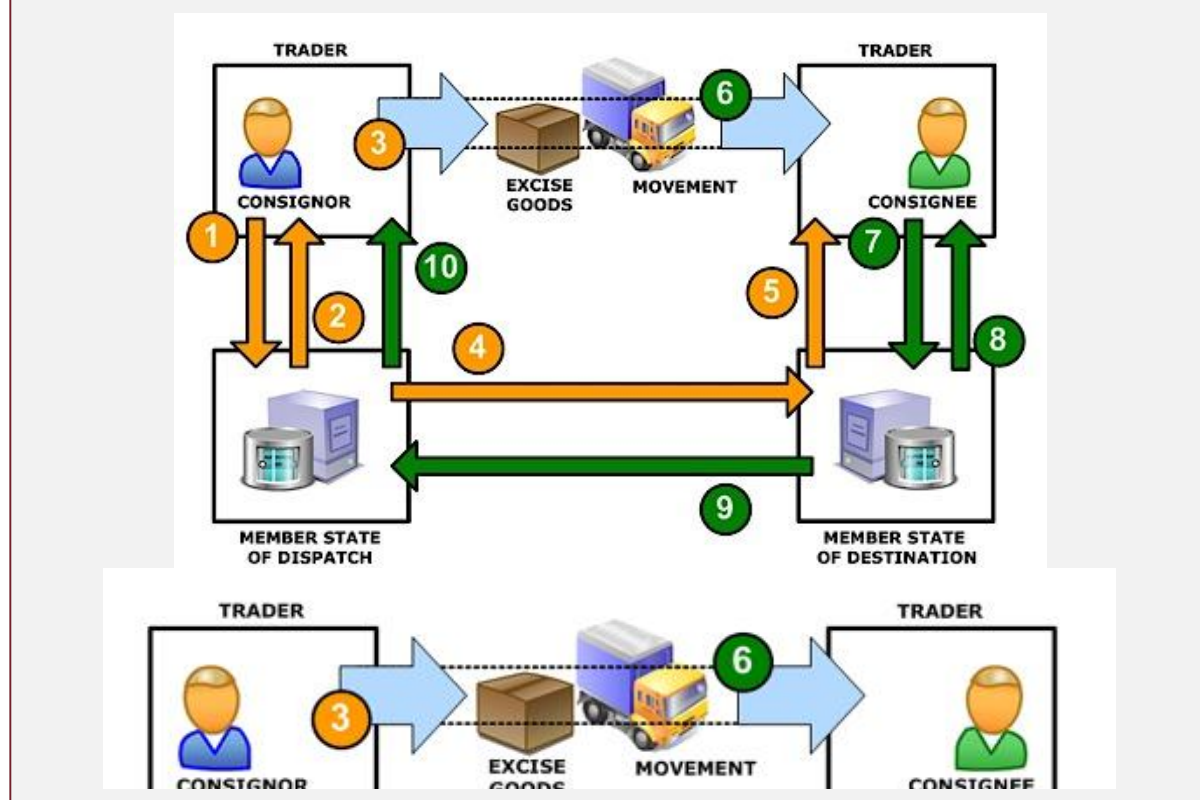
ANNEXURE 8: EXCISE MOVEMENT AND CONTROL SYSTEM

EMCS (Excise Movement and Control System) is a computerised system for monitoring movements of excise goods under suspension of excise duty within the EU, i.e. for which no excise duties have yet been paid. It replaced the paper document that accompanied such movements (the Administrative Accompanying Document or AAD) with electronic messages from the consignor to the consignee via Member State administrations.

Under EMCS, a movement of excise goods between two traders is documented by means of the successive states of the **electronic Administrative Document (e-AD)**, from issuance by the consignor to acknowledgement of receipt by the consignee.

An e-AD is electronically submitted by the consignor and validated by the Member State of dispatch. In particular, the excise numbers of the consignor and the consignee are matched against a European register of operators (SEED). The e-AD is electronically transmitted to the Member State of destination, which forwards it to the consignee. When the consignee has no connection to EMCS, he is informed by the Member State of destination or the consignor. An e-AD can be cancelled or updated under certain conditions.

Upon reception of the goods, the consignee, or another actor on his behalf, submits a "report of receipt", on which possible anomalies including shortages or excesses are also mentioned.



ANNEXURE 9: IT CONTRACT REQUIREMENTS

In addition to the specific and general service provider requirements identified in Section 10 above, the following requirements should be confirmed between the party contracting the data management service, and with the service provider, in whole or part as is appropriate. Their function is to ensure a continuity of service provision and to ensure the service is professional, secure and thorough.

A9.1. ADDITIONAL GENERAL SERVICE REQUIREMENTS FOR HOST PROVIDERS

A9.1.1. GENERAL OPERATIONS – ASSETS AND GENERAL SUPPORT

- All ICT, hardware systems, telecommunication, software, electrical supply and other assets (if any) supplied or owned by the party contracting with the data management provider in support of this agreement – including kinds, numbers and locations of assets - should be detailed in an agreed asset register.
- Any assets, including software that is the property of the party contracting with the data management provider, must be accounted for on disposal.
- Any data on any part of the system must be cleansed or sanitized under an agreed methodology prior to disposal, re-purposing or decommissioning.
- The replacement cost of any hardware or software belonging to the service provider shall be a service provider expense.
- The service provider should support its activities with a helpdesk service available for support 24 hours per day.

A9.1.2 HOST CENTRE OPERATIONS

1. Dedicated server rooms shall include the following services:
 - a. Access to off-line electrical generation capacity sufficient for two days stand-alone electrical generation.
 - b. 30-minute standby racked UPS systems.
 - c. Installed air-conditioning systems sufficient to maintain a server room average temperature of 17 degrees C.
 - d. A fire suppression system to standard FM20 or better.
2. The service provider should provide, support and service enterprise anti-virus software and firewall systems acceptable to the party contracting with the data management provider.
3. The service provider should provide, support and service automatic registry cleaning and defragmentation services on all supported servers and PCs.
4. The service provider should host on separate virtual servers to manage statistical queries and archive queries. It is acceptable to integrate these archive servers with the backup servers, but not with the production servers.
5. A separate server shall be provided for anti-virus control and definitions distribution.

6. The service provider shall provide separate physical test servers to test all software prior to deployment.
 - a. Test servers shall not be installed on the same physical servers as production servers.
 - b. Test servers shall not be used as backup servers nor shall test systems be located on the same physical servers as backup servers.
 - c. Test servers may not be substituted for or used to replace archive servers.
7. When changing a server – physical or virtual, the following operations procedures shall be followed and recorded in the operations register:
 - a. Test thoroughly with a copy of the live database.
 - b. If part of the production cluster, do not replace both servers at once – replace one of the servers in the cluster only and only after business hours have completed.
 - c. Run the server and test linkages are working correctly.
 - d. Monitor the server closely for the first day and take backups – check the database is committing correctly.
 - e. Run for a week.
 - f. Replace the second server.
8. Routers, switches, firewall devices, printers and other network and telecommunications devices shall be:
 - a. Replaced after office hours and tested for connectivity.
 - b. Checked for network conflicts before deployment.
 - c. Coordinated with Telecommunication providers
 - d. Audited every three months to ensure service log records match asset register change details.
 - e. Audited annually to confirm physical replacement SLA is being followed.
9. Should include these KPI's in additional to the standard:
 - a. Hardware acquisition, service dates and ownership details are available in the asset register.
 - b. Service control records are available in the daily operations logs.
 - c. Be available by electronic report on demand from the help desk.

A9.1.3 TIME-BASED SERVICE LEVELS

System responsiveness will be key to the collection of data from manufactures and suppliers, as well as in the processing of data. It is assumed that in most instances monitoring data is sent live by the web to an agreed data centre, or that regular data exchanges occur at set intervals via EDI (or both).

1. For the processing and manipulation of data, system responsiveness must be a specified number of (actual amount in agreement) seconds and manage a specified number of simultaneous queries and/connections.

2. For the exchange of EDI messaging in an agreed format in two directions, system responsiveness must be by an agreed number of seconds and manage an agreed number of simultaneous queries and/connections.
3. For the exchange of EDI messaging in one direction – connectivity and upload times must be less than an agreed number of seconds for an agreed number of transactions.
4. The above production response times shall also apply if:
 - a. The use of backup telecommunication links are required
 - b. The backup processing centre is used.
 - KPI's:
 - a. Average processing time reports must be maintained by day and by month and be available as part of the SLA.
 - b. Maximum processing time reports must be maintained by day and by month and be available as part of the SLA.
 - c. Failed to process numbers reports must be maintained for each day and month.
 - d. Processing system availability reports by time must be maintained for each day and by month must be maintained.
 - e. Processing system non-availability reports by time must be maintained for each day and by month must be maintained.

The above KPIs must be available as a web report to be run as required by the party contracting with the data management provider and must be available on demand from the helpdesk.

A9.1.4. TELECOMMUNICATIONS SUPPORT AND THIRD ICT PARTY SUPPORT

Given Europe's infrastructure the support requirements below should be normal to any agreement

1. The processing/host site and locations will have multiple telecommunications links. Links will be both diverse and alternately routed, with backup links being provided by different telecommunications providers.
2. Link capacity must be sufficient to meet the time-based service levels detailed above.
3. The service provider shall specify the nature, type, service levels, duration, start, renewal and termination date of its own telecommunications carriers as part of this agreement.
4. These details and the full support agreements between the service provider and any telecommunication service providers should form appendices to any SLA.

A9.1.5. REGISTERS - GENERAL

The ability to view any of the registers below should form part of any SLA. These registers are standard operations registers under all commonly accepted ICT monitoring or evaluation standards.

Even under a "Fee-for-Service" model – where the service provider is a "Black Box" or closed system, it is important for a client to have the right to view and or examine those registers to:

- Ensure agreed operations standards are being adhered to.
- Enable the client to evaluate the hosting sites performance.

Not all registers will be relevant to all agreements – for example, there would be no need to view the asset register if the party contracting with the data management provider had contributed no assets to a program. Typical registers that should be viewed include:

1. Asset Register
2. Configuration Register
3. Operations Register
4. Change Control Register
5. Third Party Service Provider Register / Service Level Agreements for Third Parties

Sample register layouts and information collected should form part of the appendices of any SLA.

Asset Register	<p>Records all the physical, software and intellectual property supported by this agreement. The register will record:</p> <ul style="list-style-type: none"> ▪ Asset Number (if no number exists one will be assigned) ▪ When items were purchased ▪ Model and make ▪ Number of drives, ram etc. ▪ Who supplied them and under what agreement ▪ When they are next due for servicing or replacement ▪ Checks undertaken to ensure functioning ▪ IP addresses if relevant ▪ Who will service them and their contact details ▪ How much they cost ▪ Where they are located ▪ Ownership of the Asset and the owners contact details. ▪ Upcoming replacement date. ▪ Software and Software IP developed, supplied or acquired by the party contracting with the data management provider under any agreement
Configuration Register	<p>The Configuration Register will record all the settings for hardware and software supported by this agreement. This includes:</p> <ul style="list-style-type: none"> ▪ Asset Number and Asset name (if any) ▪ Firmware versions and software versions for each physical Asset in the Asset Register ▪ In what order the OS, the Applications, patches and updates are to be applied. ▪ Who last applied what software patches or upgrades and when – this should be a rolling history ▪ Version control and updates records for all software supplied the agreement

<p>Operations Register</p>	<p>The Operations Register records Services that will be performed on a rolling or regular basis to keep the ICT system healthy.</p> <p>The Operations registers:</p> <ul style="list-style-type: none"> ▪ Includes sequences of Services that must be performed in a particular order and which are further specified in the Configuration Register. ▪ Who should perform them ▪ When they should be performed. ▪ What level of authority is required to perform certain Services – who is authorised to do what and who should be contacted before some Services are attempted. ▪ Policies and Procedures that must be followed before new software or hardware is introduced or modified, for example testing requirements and Acceptance requirements for new software, patches or releases.
<p>Change Control Register</p>	<ul style="list-style-type: none"> ▪ Will track and record all requests for Enhancements, Service changes, Operations changes and Bug Control fixes. ▪ When an issue has been through the Change Control process the Change Control Register shall be used to update the Operations, Asset and Configuration Registers
<p>Service Provider Register / Service Level Agreements for Third Parties.</p>	<p>Should record who has been sub-contracted by the Service Provider to do what, both externally and internally. The Register will contain the following:</p> <ul style="list-style-type: none"> ▪ The Services to be performed. ▪ When, how often and under what conditions ▪ Contract number the work is to be performed under. ▪ Contact details for the Service Provider including emergency contact details

A9.1.6 REGISTERS - NETWORK

The service provider should provide a full electronic map of the network(s) it has agreed to support and shall produce and maintain a network diagram. The network diagram shall include all sites, locations, servers, clusters, routers, switches, PCs, printers, other equipment and telecommunications relays that compose, sit on or support the network. The network map shall be updated as equipment is added and as the network changes. If no changes have occurred in the network, the service provider shall review the network configuration for improvements on a six monthly basis.

- KPI: Ability to produce a full network diagram by site and location on demand.

A9.2. MEASURING SERVICE IMPROVEMENT

Service, both internal and external, may be measured objectively. As part of any SLA or hardware supply there should be a six month review of the following characteristics:

- Reductions in help desk requests.
- Reductions in system errors to an agreed frequency and severity.
- Improvements in system availability, including response time.
- Reduction in hardware failure claims.
- Reduction in warranty calls and service and return times.

These statistics can be used as performance measures with external contractors and service suppliers as well as for internal clients.

A9.3. THIRD CONTRACTORS ENGAGED BY A SERVICE OR HARDWARE PROVIDER

As contractors, specific position descriptions do not apply, rather contractors and other service providers must fulfil minimum degrees of competency prior to hiring or appointment.

These competencies and requirements are listed in the section on service providers, in summary they should include:

- Agreement to be subject to all conditions agreed by the service provider with the party contracting with the data management provider, including all security and confidentiality agreements and obligations.
- Formal qualification in their speciality, including trade courses.
- A requirement to maintain qualifications.
- Appointment should include an annual requirement to demonstrate that skills are still current – for example rebuild a server or re-install software – as a condition of on-going appointment.
- A requirement to participate in DRP/BCP exercises and plans.
- A requirement to log all works undertaken in the appropriate registers, including daily registers if daily systems maintenance forms part of their contract conditions.
- A requirement to report all issues they might discover that could affect the party contracting with the data management provider or service provider to the service provider, even if outside their contract conditions.

A9.4. SOFTWARE SUPPLY AND CHANGE MANAGEMENT GUIDELINES

These requirements are specific to software and systems control providers, including providers of remotely accessed or controlled hardware systems. Initial and on-going requirements collection should be a joint service between the party contracting with the data management provider and the software/hardware supplier. The following processes will be observed:

A combined service provider/requirements team:

- Will confirm the need for the change to the system.
- Verify the legality of any proposed change.
- Enter the proposed changes in to the change control register.
- Evaluate the operational impact of the proposed change on all parties, including tobacco manufacturers and suppliers.
- Collect further requirements and produce a business specification.
- Confirm the changes and business specification with relevant business units, tobacco manufacturer or supplier and party contracting with the data management provider senior management.
- Produce an initial budget estimate and implementation time frame/strategy.
- Submit the request to the service provider for discussion, evaluation and costing.

The Service Provider shall then:

- Evaluate the request technically, operationally and financially.
- Advise on cost, impact and feasibility, including costs and obligations that may be incurred by tobacco manufacturers and suppliers.
- Advise a development timeframe and negotiate an implementation and cost plan with the party contracting with the data management provider.
- Program the changes if the process moves forward.
- Be responsible for all white box testing, unit and integration testing.

The party contracting with the data management provider and service provider shall then jointly:

- Verify that the proposed changes meet the users requirements.
- Perform secondary unit and integration testing. This testing must include testing by the business unit that requested changes, other affected business units and tobacco manufacturers and distribution chain economic operators (if appropriate).
- Amend, test and re-test as required.

The party contracting with the data management provider and service provider should then jointly:

- Perform acceptance testing.
- Following acceptance, deploy to the business along the lines agreed to with service provider and the businesses, using external staff and advisers as needed.

Update all configuration, asset and operation files and registers.

ANNEXURE 10: REFERENCE TABLES USED IN COST BENEFIT ANALYSIS

TABLE 1: NUMBER OF BIG DISTRIBUTORS AND WHOLESALERS, BY COUNTRY

	# Wholesalers
POLAND	404
ROMANIA	90
UNITED KINGDOM	63
SPAIN	49
ITALY	98
SLOVENIA	5
GREECE	378
GERMANY	422
PORTUGAL	261
CZECH REPUBLIC	0
FINLAND	10
IRELAND	50
SWEDEN	84
LITHUANIA	6
NETHERLANDS	58
MALTA	32
BELGIUM	72
ESTONIA	6
DENMARK	19
SLOVAKIA	18
CYPRUS	19
AUSTRIA	13
LUXEMBURG	11
LATVIA	12
FRANCE	26
BULGARIA	200
CROATIA	23
HUNGARY	21
Total EU, 2012	2 450

Source: EUROSTAT 2012

TABLE 2: HR ADDITIONAL COSTS ON WAREHOUSES CALCULATION FOR DISTRIBUTION CHANNEL

	Min Wages in 2013	Incremental costs -A-
POLAND	404 €	10 404 573 €
ROMANIA	205 €	1 218 115 €
UNITED KINGDOM	1 301 €	6 408 763 €
SPAIN	753 €	2 897 890 €
ITALY	753 €	2 863 116 €
SLOVENIA	789 €	2 672 063 €
GREECE	684 €	2 200 642 €
GERMANY	1 469 €	4 522 710 €
PORTUGAL	566 €	1 219 808 €
CZECH REPUBLIC	310 €	505 842 €
FINLAND	1 469 €	1 515 108 €
IRELAND	1 462 €	1 485 382 €
SWEDEN	1 469 €	1 424 654 €
LITHUANIA	290 €	174 104 €
NETHERLANDS	1 486 €	823 509 €
MALTA	718 €	386 847 €
BELGIUM	1 502 €	786 133 €
ESTONIA	355 €	125 691 €
DENMARK	1 469 €	271 363 €
SLOVAKIA	352 €	65 024 €
CYPRUS	697 €	107 295 €
AUSTRIA	1 430 €	66 040 €
LUXEMBURG	1 921 €	88 715 €
LATVIA	320 €	14 778 €
FRANCE	1 445 €	845 276 €
BULGARIA	174 €	2 679 €
CROACIA	398 €	0 €
HUNGARY	328 €	0 €
		43 096 117 €

- Average number of people doing shipping operations

- Number of wages per year considered

- % of HR incremental costs considered

Data-Source: "THE EUROPEAN TOBACCO SECTOR – An analysis of the socio-economic footprint"; printed by Nomisma; Bologna/Italy in June 2012; E.T.V.; Euromonitor; own calculations

TABLE 3: NUMBER OF VENDING MACHINES SERVICE VANS OPERATING IN THE EU, BY COUNTRY

	Vending machines	Vending Machines service vans
SPAIN	175 000,0	552,6
ITALY	13 850,0	43,7
GERMANY	380 000,0	1 200,0
PORTUGAL	61 000,0	192,6
CZECH REPUBLIC	4 000,0	12,6
NETHERLANDS	16 400,0	51,8
MALTA	2 400,0	7,6
BELGIUM	12 300,0	38,8
AUSTRIA	6 000,0	18,9
LUXEMBURG	900,0	2,8
Total EU, 2010	671 850,0	2 121,6
Market evolution 2010 - 2013		-8,4%
Total EU, 2013		1 944,1

Source: E.T.V. - Sovereign border solutions Mönchengladbach, 12th August 2014

TABLE 4: HR ADDITIONAL COSTS ON VENDING MACHINES SERVICE VANS CALCULATION FOR DISTRIBUTION CHANNEL

	Vending machines	Vending Machines service vans	Min Wages in 2013	Incremental costs
SPAIN	175 000	553	753 €	2 330 337 €
ITALY	13 850	44	753 €	184 430 €
GERMANY	380 000	1 200	1 469 €	9 871 680 €
PORTUGAL	61 000	193	566 €	610 565 €
CZECH REPUBLIC	4 000	13	310 €	21 928 €
NETHERLANDS	16 400	52	1 486 €	430 971 €
MALTA	2 400	8	718 €	30 473 €
BELGIUM	12 300	39	1 502 €	326 709 €
AUSTRIA	6 000	19	1 430 €	151 731 €
LUXEMBURG	900	3	1 921 €	30 574 €
Total EU, 2010	671 850	2 122		13 989 398 €
Market evolution 2010 - 2013			-8,4%	
Total EU, 2013			1 944	
- Average number of people doing shipping operations			1	
- Number of wages per year considered			14	

Source: E.T.V. - Sovereign border solutions Mönchengladbach, 12th August 2014

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